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Issues in Medical Waste Management

Background Paper

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Foreword

During the summer just passed, we witnessed a rash of incidents in which medical wastes washed ashore—from Maine to the Gulf of Mexico, along the Great Lakes, and elsewhere in the Nation. These and other incidents, which were the focus of intense media coverage, drew public attention to issues surrounding the management of medical wastes.

Waste management in general has become a common headline topic. We hear daily about declining landfill capacity, problems in siting new incinerators, and efforts to increase recycling. OTA's ongoing assessment of municipal solid waste management is addressing these issues.

As part of the assessment, OTA also examined the status of medical waste management in the Nation. OTA held a one-day workshop on July 19, 1988, with hospital, regulatory, and environmental experts to review the initial draft of this background paper and to discuss other areas of interest. The conclusions of those discussions have been incorporated in this paper.

The paper examines the adequacy of current medical waste disposal practices and the potential for human health impacts to occur as a result of such practices. It also addresses the need for additional research and databases, and discusses probable trends in future costs and capacity as new regulations are adopted around the country. Finally, the paper considers the possible need for further Federal involvement in regulating the handling, treatment, storage, and disposal of medical wastes.

OTA is grateful for the input from the workshop participants and other reviewers. The preparation of this paper would have been much more difficult without such support. As with all OTA studies, the content of this paper is the sole responsibility of OTA.

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Introduction

- Without advance notice, on March 24, 1986, the GSX waste handling company informed eight Boston, Massachusetts, hospitals that it would no longer pick up any of their hospital wastes because the area landfills would no longer accept them. For two of these hospitals, GSX did not even handle their "red bag" waste (44).
- Approximately 1,400 bags of medical waste were discovered at a warehouse by the New York City Fire Department when it responded to a fire November 24, 1986. Subsequently, the Energy Combustion Corporation and its president were indicted by the Brooklyn District Attorney's Office for allegedly covering up this illegal dumping. The company had submitted documents to the New York State Department of Environmental Conservation stating that the wastes had been incinerated (21).
- Twelve children in Indianapolis, Indiana, played with vials of blood, two of which were infected with AIDS, that they found in a trash bin outside an HMO medical office in June 1987. It was legal for the health clinic to dispose of the wastes in the open dumpster (27).
- Five employees of the Los Angeles County-USC Medical Center filed a $50 million lawsuit against the county after a pipe in the basement of the facility burst on July 9, 1987, and dumped possibly contaminated blood and fluids on workers. The California Occupational Safety and Health Administration has received other complaints concerning the adequacy of protection provided for employees handling medical wastes at the Center (56).
- A garbage slick nearly a mile long along the shore in Ocean County, New Jersey, on May 23, 1988, marked the first slick of the season. Needles, syringes, and empty prescription bottles with New York addresses washed up on the shore (31). New Jersey beaches closed several times last season due to such incidents. More recently, on July 6-7, 1988, 10 miles of Long Island beaches closed when medical wastes washed ashore. Throughout the summer of 1988, beaches from Maine to the Gulf of Mexico, along the Great Lakes, and elsewhere in the Nation experienced washups of medical wastes.

Recent incidents such as these have drawn attention to issues surrounding the handling, treatment, and disposal of medical wastes. Medical wastes are *all* the types of wastes produced by hospitals, clinics, doctor offices, and other medical and research facilities.[1] These wastes include infectious or "red bag" hospital wastes, hazardous (including radioactive) wastes, and any other general wastes.[2] The Environmental Protection Agency reports that approximately 3.2 million tons of medical wastes from hospitals are generated each year, which is about 2 percent of the total municipal solid waste stream.[3] Currently, most generators of medical waste designate between 10 to 15 percent of it as infectious.

Most of the non-infectious medical waste is landfilled, while most infectious waste from hospitals is incinerated. For infectious waste management, an American Hospital Association survey reported in 1983 that approximately 67 percent of U.S. hospitals use on-site incinerators, 16 percent use only autoclave (i.e., sterilization) systems and then landfill, and approximately another 15 percent use offsite treatment (9,62). The degree of risks posed by medical wastes is not known. Proper handling, treatment, and disposal of these wastes are believed to result in minimal health and environmental risks. Yet, incidents of careless or illegal disposal may pose health risks and aesthetic problems and certainly help create public apprehension over current medical waste management practices.

---

[1]This would also include wastes from research laboratories, biotechnology firms, veterinary hospitals, funeral homes, nursing homes, etc. Most of the public and regulatory attention has been focused on hospital waste disposal; however, other sources of biomedical wastes may be equally significant. Although this paper will also tend to focus on hospitals and larger sources of medical wastes, given that there is more readily available information on these facilities, the need for assessing the importance of smaller generators of biomedical wastes is recognized.

[2]The terms medical wastes, hospital wastes, infectious wastes, and biomedical wastes often are used interchangeably. An attempt is made here to use these terms more precisely, i.e., the term medical wastes refers to all types of wastes produced by a hospital or any type of facility; hospital wastes refers to all wastes produced by a hospital; infectious wastes refers to that portion of a medical wastestream which has the potential to transmit disease; and biomedical wastes are the subset of medical waste which is biological in origin (e.g., blood, body fluids, tissue, etc.).

[3]Estimates range from 2.1 to 4.8 million tons per year. As will be discussed below, these figures do not include medical wastes from clinics, laboratories, and other sources. It is likely, therefore, that medical wastes comprise a somewhat higher—although still relatively small—percentage of the total municipal solid wastestream.

Just as the types of incidents listed above raise public concern, considerations of liability and worker safety lead some operators of municipal solid waste landfills and incinerators to ban or refuse to take any medical wastes. A number of States have banned all unsterilized infectious waste from municipal landfills.[4] In addition, the State of Pennsylvania has imposed a one-year moratorium on the construction of any commercial medical waste incinerators.[5] In other areas, localities as well have considered bans or moratoriums on hospital waste incinerators.[6] In this general context, many hospitals, medical facilities, and other institutions across the country face increasingly difficult waste management problems.

The situation is complicated by an uncertain and incongruous regulatory climate. Inconsistencies exist in the Federal guidelines for States regarding definitions and management options suggested for medical/infectious waste.[7] Currently, no Federal regulations exist that comprehensively address the handling, transportation, treatment, and disposal of medical waste. This would change either if the issue of medical wastes remains part of the current reauthorization effort for the Resource Conservation and Recovery Act (RCRA)[8] or if any of a number of bills introduced in Congress relating to medical waste issues (see discussion below) pass.

Meanwhile, the States have largely been left on their own to devise medical waste management programs. This means important variation frequently exists between States, as well as between local requirements and those of a State. For example, 26 States classify infectious wastes as special wastes, 13 still classify them as hazardous wastes, and 12 classify them as non-hazardous wastes (4).[9] Thirty-nine States have some type of regulations concerning infectious waste, at least 5 more States expect to regulate these wastes within the year; and at least 25 States expect changes to their existing regulations by next year (4).[10]

The purpose of this paper is to assess the adequacy of current medical waste disposal practices; the potential risks from such practices; the need for additional research and databases; and the possible need for Federal requirements for the handling, treatment, storage, and disposal of medical wastes and future cost and capacity factors as new regulations are updated. The paper is divided into five chapters:

1. Defining and Characterizing Medical Wastes;
2. Handling Medical Wastes and Potential Occupational Risks;
3. Current Technologies, Treatment, and Disposal Issues;
4. Regulatory Authority and Current Practices; and
5. Managing Medical Wastes—Institutional and Policy Issues.[11]

[4]In some areas, if medical wastes of any sort are accepted, an inspection fee in addition to the tipping fee is charged. For example, the town of Brookhaven, New York, banned University Hospital's waste three times in a 6-month period due to alleged contamination problems. The agreement reached between the town and the hospital requires the hospital to pay $15 per compacted load for inspection of the wastes and reserves the town's right to ban the hospital's waste if there are future violations (24).

[5]The Pennsylvania Department of Environmental Conservation had lifted a moratorium on permitting hospital incinerators in February 1988. In July the State legislature imposed a one-year moratorium on permitting new commercial hospital incinerators. The current moratorium will be lifted when the Department completes a comprehensive plan for medical wastes which is due July 13, 1989. Other States (e.g., Delaware) have or are considering similar moratoriums.

[6]Although the exact number of such landfill refusals or bans are not known, discussions with a number of individuals across the country involved with medical waste management indicate that these practices are not uncommon and appear to be increasing in frequency. E.g., references 23 and 28.

[7]As will be discussed below, the Environmental Protection Agency, Centers for Disease Control, and other Federal agencies have issued different guidelines for infectious and medical waste management.

[8]42 U.S.C. 6901 et seq.

[9]Note that the survey includes the District of Columbia; for this reason, figures add up to 51. See below for further discussion of this aspect of the definitional issue. Under RCRA, there are two general categories of wastes, each of which is subject to different regulatory requirements. These are hazardous wastes regulated according to Subtitle C, and solid (non-hazardous) wastes regulated according to Subtitle D. In addition, there is a third, non-statutory category of "special wastes" for those wastes that appear to be in a gray area between these two categories and for which special regulatory programs will be established.

[10]Compare results of slightly older survey, reported earlier in 1988 by the National Solid Waste Management Association (51).

[11]Specific, basic information is often lacking or at present not available to OTA on a number of important topics, and these areas are noted below.

Chapter 1
Defining and Characterizing Medical Wastes

Medical wastes include all infectious waste, hazardous (including low-level radioactive) wastes, and any other wastes that are generated from all types of health care institutions, including hospitals, clinics, doctor (including dental and veterinary) offices, and medical laboratories (42).[1] The main focus of concern has been on the portion of medical wastes that are defined as infectious, and how they are classified (e.g., as a solid, hazardous, or "special" waste) and regulated. These wastes are also the primary focus of this paper. The main sources of these wastes receiving attention are hospitals and other large facilities. Much of the information reported here will focus on these larger generators, but the proper disposal of other types of medical wastes and of wastes from all types of sources is also important.[2]

Amounts and Composition

The actual amount of medical waste generated in the United States today (or in the past) is not known; even estimating this figure is problematic, as the number of different reported estimates indicate. In 1987, the Environmental Protection Agency (EPA) reported the total generation rate of *hospital* wastes at 5,900 tons/day (83). This figure is based on the number of hospital beds estimated to exist (in 1985, the estimate was 1.3 million with a 69 percent occupancy rate) and a per bed per day generation rate of 13 pounds.

The per bed per day generation figure itself, however, is difficult to pinpoint. Recent independent estimates of hospital waste generation range between 16 to 23 pounds per bed per day (61). The range reported by hospitals in various surveys of hospital waste generation is 8 to 45 pounds per bed per day.[3] EPA expected the 13 pound per bed per day rate to remain constant, as it believes it did for the period from 1975 to 1985 (83). In 1980, however, one survey of North Carolina hospitals reported an average of approximately 10 pounds per bed per day of wastes. If this lower figure was typical in years past, then it would indicate that the amount of per bed generation of hospital wastes *may* have increased significantly within the last decade. Healthcare workers and administrators do indicate that the amount of disposable items used in hospitals and other medical facilities has increased dramatically in recent years, although data are not available to document this observation.

Few data are available on the composition of hospital waste, although it is characteristically heterogeneous in nature. The mix of materials includes, in addition to general refuse (e.g., office paper, food waste, non-infectious patient waste) and infectious waste (e.g., pathological wastes, human blood and blood products, contaminated sharps and anatomical wastes, isolation wastes), hazardous wastes (e.g., waste pharmaceuticals, cytotoxic agents used in chemotherapy, mercury or other heavy metals), and radioactive wastes.[4]

The composition of the medical wastestream is of concern given its effects on the incineration process. If incineration occurs on-site, it is likely that at least some of the hospital or facility's wastes are mixed (if wastes are shipped off-site, given the greater expense of treating infectious waste this

[1]See also ref. 39. It should be noted that extensive treatment of the current management of radioactive and other identified hazardous wastes in the medical wastestream is beyond the scope of this paper. It is recognized, however, that proper management of such wastes is important and a challenge for many medical waste generators, given the usually small quantities and high cost of adequate disposal of these wastes.

[2]The amount of medical wastes from such non-hospital sources is not known. Other sources of infectious wastes, such as sewage overflows, can also be a significant source of environmental contamination (e.g., impacting beaches and shellfish areas), but are beyond the scope of this paper.

[3]Different methodologies to calculate per bed generation figures, may explain the wide variation in estimates. Also, of course, the actual hospital generation figures can vary greatly on a daily basis. Some surgical procedures generate much more waste (e.g., a heart transplant) than other routine operations (83). In addition, difficulties in segregating infectious and non-infectious wastes may lead to more mixed waste disposal that is treated as infectious.

[4]It should be noted here that not all of these hazardous or toxic wastes are regulated by the Resource Conservation and Recovery Act (RCRA), and, in addition, many of the generators of these wastes may qualify for a small quantity generator exemption from RCRA requirements (e.g., this would include most hospitals under 200 beds). Nonetheless, if some of these wastes are incinerated on-site they could be a source of air emission concern (83).

way, it is likely that only infectious waste is sent for incineration).[5] Particular components of the medical wastestream of special concern when this waste is incinerated include the relatively high plastic content of medical waste (to be discussed further below). About 20 percent of the hospital wastestream is estimated to be plastics (83), which is about three times the plastic portion of the municipal solid wastestream.[6]

In any case, reported generation figures do not include non-hospital medical wastes. In 1985, approximately 6,870 hospitals and an estimated 1,000 diagnostic and research laboratories existed, in addition to thousands of doctor offices and nursing homes (5).[7] Although specific estimates are not available on the volume or composition of medical wastes from these sources, it is reasonable to expect that the *total* medical waste generation (both hospital and non-hospital) figure is somewhat higher.

Designating Infectious Waste

Determining which portion of medical waste is infectious goes to the heart of the definitional problems associated with medical waste management. There are two basic sources that hospital and other medical facilities may use in determining their working definition of infectious wastes: EPA guidelines and Centers for Disease Control (CDC) guidelines. These will be discussed below.

How infectious waste is defined can greatly affect the cost of waste management, and ultimately the choice of waste management disposal options for generators. For example, one 600-bed hospital found that it saved $250,000 annually by changing its infectious waste designation from 13 categories to the 4 designated by the CDC (59). General cost figures for disposal are (approximately): $0.01 to $0.25/lb. for general refuse/non-infectious waste (usually landfilled); $0.10 to $0.25/lb. for incineration on-site (includes infectious wastes);[8] and 0.30 to 1.00/lb. (although costs may be higher in some areas) for commercial, off-site incineration (6,10).

Most estimates are that 10 to 15 percent of *all* hospital wastes are infectious. The total range of estimates, however, is from 3 to 90 percent of a hospital's waste defined as infectious, depending on the definitions and procedures followed (10,83). According to Lawrence Doucet, a consultant on hospital waste management, about 3 to 5 percent of a hospital's total wastestream would be classified as infectious waste according to previous interpretations of CDC guidelines for infectious wastes, while approximately 10 percent would be classified that way according to the 1986 EPA guidelines (10).[9]

The recommendations issued by CDC in August 1987, however, have apparently been interpreted by some hospitals as classifying virtually all patient-contact waste as infectious (77). This can amount to 70 to 90 percent of total hospital waste. **The potential impact of such a trend on medical waste management could be to both increase the cost of disposal significantly and strain existing capacity for managing infectious wastes.** The CDC has issued a clarification of its definition, yet confusion at the generator level appears to remain over the proper classification and management of medical wastes (78).

Definitional Differences—EPA v. CDC

William Rutala, University of North Carolina School of Medicine (Director of the Statewide Infection Control Program), has noted that no tests exist to objectively identify infectious wastes, unlike the case with chemical or radiological wastes (60).[10] This has led the CDC, EPA, States, and other agencies to identify and further define infectious waste by waste category based on waste characteristics.

EPA defines infectious waste as "waste capable of producing an infectious disease" (81). Coupled

[5]Actual data on the amount of waste incinerated on-site v. off-site, and whether waste is usually mixed or not, are not currently available.

[6]Estimates of the portion of plastics in hospital waste range as high as 30 percent.

[7]See also ref. 10.

[8]It should be noted that capital costs, depreciation, and other types of costs may not be included in these figures.

[9]Interestingly, a recently completed survey for the American Hospital Association reported that 80 percent of the hospitals are following CDC guidelines, while only 52 percent are complying with EPA guidelines (to be discussed further below) (61).

[10]See also ref. 70.

with the definition is the need to consider at least four factors necessary for the induction of disease:

1. presence of a pathogen of sufficient virulence,
2. dose,
3. portal of entry, and
4. resistance of the host.

Thus, the Agency notes that:

> . . . for a waste to be infectious, it must contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease (81).

The CDC recommendations, issued in August 1987, and referred to as "universal precaution" procedures, are essentially that blood and body fluids from "*all* patients be considered potentially infected with HIV (human immunodeficiency virus) and/or other blood-borne pathogens and [that health care workers] adhere rigorously to infection-control precautions" (77). In June 1988, the CDC attempted to clarify several issues associated with apparent confusion over the application of their 1987 recommendations. As part of this effort, the CDC now limits the application of universal precautions to blood and other body fluids containing visible blood, to semen and vaginal secretions, and to other specified fluids (78). The CDC also notes that the recommendations are intended to protect healthcare workers and do not address waste management practices or the definition of infectious wastes (78).

Both the CDC and EPA designate pathological waste, blood and blood products, contaminated sharps (e.g., scalpels, needles, blades), and microbiological wastes (e.g. cultures and stocks) as infectious. Some apparent disagreement exists between the designations of and suggested treatments for different components of infectious wastes identified by the CDC and EPA. (See table 1.) EPA has identified several additional optional categories, which include a category of isolation wastes, a category of contaminated animal carcasses, body parts, and bedding, and categories of surgery, autopsy and contaminated laboratory wastes (81). The apparent inconsistencies are remedied in part by the fact that EPA refers to the CDC guidelines on isolation precautions (74) and to the joint CDC/National Institutes of Health guidelines on animal carcasses waste management and other guidelines on laboratory wastes.[11]

[11]Although the CDC does not classify animal carcasses as infectious wastes, the CDC/National Institutes of Health guidelines, "Biosafety in Microbiological and Biomedical Laboratories (75)," recommend incineration of infected animal carcasses and decontamination (preferrably by autoclaving) before disposal for all wastes from animal rooms of certain designated biosafety levels

Table 1.—CDC/EPA Designations of Solid Wastes and Recommended Treatment/Disposal Methods

	CDC[a]		EPA	
Source/type of solid waste	Infectious waste	Disposal/ treatment method	Infectious waste	Disposal/ treatment method
Microbiological (e.g., stocks and cultures of infectious agents)	Yes	S,I	Yes	S,I,TI,C
Blood and blood products (i.e., liquid blood and blood products)	Yes	S,I,Sew	Yes	S,I,Sew,C
Communicable disease isolation	Yes/No	HP	Yes	S,I
Pathological (e.g., tissue, organs)	Yes	I	Yes	I,SW,CB
Sharps (e.g., needles)	Yes	S,I	Yes	S,I
Contaminated animal carcasses, body parts and bedding	No	—	Yes	I,SW (not bedding)
Contaminated laboratory wastes	No	—	Optional[b]	If considered IW, use S or I
Surgery and autopsy wastes	No	—	Optional	If considered IW, use S or I
Dialysis unit	No	—	Optional	If considered IW, use S or I
Contaminated equipment	No	—	Optional	If considered IW, use S or I

[a]Abbreviations: CDC—Centers for Disease Control; EPA—Environmental Protection Agency; I—Incineration; S—steam sterilization; TI—thermal inactivation; C—chemical disinfection for liquids only; Sew—sanitary sewer (EPA requires secondary treatment); HP—in accordance with hospital policy; SW—steam sterilization with incineration or grinding; CD—cremation or burial by mortician; IW—infectious waste.
[b]Optional infectious waste: EPA states that the decision to handle these wastes as infectious should be made by a responsible, authorized person or committee at the individual facility.

SOURCE: W. Rutala, "Infectious Waste—A Growing Problem for Infection Control," *ASEPSIS: The Infection Control Forum* 9(4):2-6, 1987.

The major *apparent* disagreement is over the designation of communicable disease/isolation wastes. Although the CDC and EPA agree that there is no inconsistency in their designations of these wastes, confusion exists in the application of these guidelines. This may indicate a need for further clarification of these guidelines by the two agencies. EPA considers communicable disease wastes as infectious. CDC recommends that communicable disease waste be treated according to hospital policy (74). Nelson Slavik notes, in his report of the proceedings of the EPA Infectious Waste Management Meeting held in November 1987, that recent interpretations by hospitals and other generators of the CDC universal precaution guidelines, and the concern over potential exposure to AIDS, can result in any blood or body fluid and any item contaminated with them being designated as infectious waste.

Previously, only patient waste from those patients in isolation would be included in the EPA's infectious waste definition; interpretation of the CDC guideline, however, could include *all* patient contact wastes and wastes of EPA's optional category (e.g., surgical and autopsy wastes, dialysis waste, contact laboratory wastes) in the infectious waste definition (70). The CDC disputes this interpretation of its recommendations (77,78). The CDC issued a statement in June 1988 that,

> Universal precautions are not intended to change waste management programs previously recommended by CDC for health-care settings (78).[12]

This attempt at clarification by CDC, however, in part contributes to the confusion. It is not clear why the CDC is suggesting that its universal precautions guidance applies only to worker precautions and not waste handling procedures.

EPA agrees with CDC that its recommendations are not in serious disagreement with EPA recommendations and that universal precautions are meant to protect healthcare workers and do not "attempt to define what is infectious waste" (87). Given the state of confusion at the generator level, though, further clarification and perhaps *jointly issued guidance* on these definitional issues is desirable.

Currently, based on the proceedings of the EPA meeting of experts on infectious wastes held in November 1987, there appears to be agreement that:

> Not withstanding the risk perceptions and anxieties associated with the fear of contracting AIDS, those categories of infectious wastes that possess the greatest potential to transmit disease are contaminated sharps, human blood and blood products, pathological wastes (primarily body fluids), and laboratory wastes (70).

The position is that, given the consistent recognition of the potential hazards from these wastes, either due to known disease association or risk of accidental injection, their "prudent" handling and proper disposal are warranted (70). EPA did, however, solicit comments regarding the basis on which wastes should be defined as infectious and is currently reviewing its definition of infectious wastes.[13]

Classifying Infectious Waste as Hazardous Waste

Additional confusion arises over the question of whether or not infectious wastes should be classified and regulated as Subtitle C, RCRA hazardous wastes. In 1978, EPA did include regulations for infectious wastes in its proposed hazardous waste regulations. The Agency never promulgated these, however, and has not classified any infectious wastes as hazardous wastes—even though the language of RCRA includes "infectious" as a characteristic to be considered in determining whether or not a waste is a hazardous waste.[14] The statu-

[12]According to the CDC, for example, blood, some body fluids, and sharps from an isolation room should be handled as if potentially infectious, but not *all* wastes from this type of room. CDC further states that, "While any item that has had contact with blood, exudates, or secretions may be potentially infectious, it is not usually considered practical or necessary to treat all such waste as infective" (78).

[13]53 *Federal Register*, June 2, 1988. The EPA published a notice of data availability and request for comments on infectious wastes issues. Comments were due August 1, 1988 and the Agency received over 100 responses. EPA is now in the process of responding to and summarizing these comments as part of its consideration of possible regulatory action for medical wastes (86).

[14]RCRA (Public Law 94-580), in Section 1004 (codified as 42 U.S.C. 6903(5)), includes the following definition:

> (5) The term "hazardous waste" means a solid waste, or combination of solid wastes, which because of its quantity, concentration, physical, chemical, or *infectious* characteristics may—
>
> (A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed [emphasis added].

tory language can be interpreted as requiring these wastes to be classified as hazardous and thus regulated under Subtitle C of RCRA.

EPA, based largely on its determination of a lack of evidence that infectious wastes "cause harm to human health and the environment" sufficient to justify Federal rulemaking (under Subtitle C, RCRA), has instead issued a manual of recommendations for the management of infectious wastes (81). It should be noted, however, that the statutory language refers not only to whether a waste will "*cause* harm," but also to whether it may "*pose* a substantial present or potential hazard . . ." (emphases added; RCRA, Section 1004).

Even so, 12 years after the passage of RCRA and 8 years after making the determination that insufficient evidence existed to justify Federal regulation, EPA has not undertaken or encouraged research to substantiate a lack of "a substantial present or potential hazard to human health or the environment" when a waste with infectious characteristics is improperly managed (a criterion of RCRA, Section 1004(5) definition of hazardous waste). Alternatively, the Agency has not issued its assessment, based on existing epidemiologic information, of the degree of risk posed by infectious or other types of medical wastes.

To date, EPA's actions have not been legally challenged. Congress may clarify the conditions under which medical wastes are to be regulated as part of the current RCRA reauthorization process. Currently, the Agency considers medical waste a solid waste subject to RCRA, Subtitle D regulation and is in the process of addressing the need for additional regulations to control infectious wastes.[15] EPA did include a space for infectious waste on the "Notification of Hazardous Waste Activity" form, which is used by hazardous waste generators to apply for EPA identification numbers, but no paragraph addressing infectious wastes actually exists in the regulations referenced on the form.[16]

Interestingly, a manual published by the Joint Commission for the Accreditation of Hospitals (JCAH)[17] designates infectious wastes and sharps as hazardous wastes, along with chemical, chemotherapeutic, and radioactive wastes. The manual outlines methods for handling each type of waste, and the JCAH requires that a system to handle all such hazardous wastes exist and be in compliance with Federal, State, and local regulations (34).[18] In addition, the National Committee for Clinical Laboratory Standards (NCCLS) in its proposed guideline for clinical laboratory hazardous waste includes infectious waste (i.e., waste with "infectious characteristics," following the RCRA, Section 1004 definition) in its definition of hazardous waste (49,50). **From a generator perspective, greater consistency on the classification of infectious and other medical wastes would help eliminate some of the current confusion over the proper treatment of these wastes.**

A policy debate continues over how best to classify infectious wastes, and other medical wastes, as well. Some observers, noting the likely increase in cost as more wastes become designated as infectious, expect even more costly disposal if in addition these wastes must be handled as hazardous. Further, concerns over the difficulty of siting hazardous waste facilities are noted. Others maintain that hospital disposal costs are likely to increase due to increased regulation in general and focus instead on the most reliable waste disposal options. Arguments over the difficulty of siting hazardous waste are countered by those who point out that any type of waste facility is difficult to site (although successful siting of facilities does occur when public participation and other measures are included in the site selection process). In addition, hospitals may continue to treat wastes on-site (if, for example, they have the space to upgrade or construct facilities).

Classifying infectious wastes as hazardous is seen as desirable by some in order to prosecute illegal dumping as a felony, to bring in force a manifest system for infectious wastes which would track the off-site movement of these medical wastes (21,22), and in general to ensure greater comprehensive management of infectious wastes.[19] These purposes

[15]40 CFR 240.101. (See refs. 73,86.)

[16]EPA Form 8700-12, revised November 1985, referencing 40 CFR 261.34.

[17]Recently, JCAH changed its name to the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).

[18]As Rutala (60) points out, since there are no Federal regulations, hospitals must comply with State and local regulations; if these do not exist, then hospitals should comply with either CDC or EPA guidelines.

[19]New York State recently passed legislation which both provides for penalties of up to 4 years in prison and fines of up to $50,000 for illegal disposal of medical wastes (previously the penalties were up

could be accomplished without classifying infectious wastes as hazardous wastes (some of these issues will be discussed further below). Yet, proponents for regulating infectious wastes as a hazardous waste argue that to do so is likely to be the most expeditious approach to the problem (rather than risk delay and confusion created by developing another system). Furthermore, it is not clear how much flexibility the EPA has under RCRA to address infectious waste as a waste type other than hazardous.[20] Again, this issue could be clarified as part of the current reauthorization effort in Congress.

Uncertainties for State Regulators

These definitional and classification problems have created considerable uncertainties for State regulators. Approximately 10 States have definitions of infectious waste which include the four common CDC and EPA infectious wastes in their definitions (i.e., pathological wastes, microbiological wastes, blood and blood products, and contaminated sharps).[21] As noted above, most States designate infectious wastes as special wastes, and the trend is for other States to do the same. Previously, infectious wastes were classified by States as hazardous wastes because of the aforementioned RCRA definition. In fact, States must have a program no less stringent than the Federal Government's. Since the EPA has not regulated infectious wastes as hazardous, the trend seems to be for the States not to do so, too.[22] States apparently find the delisting of a hazardous waste after it has been treated to be a particularly cumbersome and difficult aspect of regulating infectious wastes as hazardous wastes (4).

to 15 days in jail and up to $2,500 in fines) and establishes a manifest system to track medical wastes. Several bills pending in Congress also would classify illegal dumping of medical wastes as a felony and specify penalties. The Senate passed legislation to establish a model manifest program for several States in the Northeast; similar legislation is pending in the House (see ch. 5).

[20]See 42 U.S.C. 6903(5) and 6921.

[21]53 *Federal Register*, June 2, 1988.

[22]Although some States and localities have moved beyond whatever a "baseline" Federal definition of infectious wastes might be, such a consistent definition might facilitate the development of other Federal regulations of infectious wastes.

Chapter 2
Handling Medical Wastes and Potential Occupational Risks

The degree of risks posed by medical wastes is not clear. Two main types of risks associated with medical wastes can be distinguished: occupational and environmental. Occupational exposure to health workers and waste handlers is often cited as the primary type of health risk posed by medical wastes. Yet, precise information on the types and frequency of actual occupational injuries or illnesses due to handling medical wastes is not readily available.[1] Environmental risks can be posed directly by illegal or careless management and disposal practices or more indirectly through the emissions and ash handling from medical waste incinerators.[2]

In this context, questions regarding the significance of all—large and small—generators of medical wastes become important. This section first describes the general nature of *handling* (including initial handling, storage, and transportation) of medical wastes and the types of risks associated with it, and then discusses the potential magnitude of these risks. What is known about the possible risks associated with incineration and other treatment methods for medical wastes will be discussed in subsequent chapters.

Handling: Packaging, Storage, and Transportation

Handling medical wastes—including initial handling, storage, and transportation—involves issues of potential occupational risks and potential operational problems. Improper handling of medical wastes is closely linked to problems resulting from inadequately packaged and contained wastes as they move about the hospital and then are transported off-site for disposal. The integrity of packaging, particularly of such items as sharps, is critical to ensuring the containment of wastes during their collection, storage, and transportation.

Packaging

Polyethylene bags are frequently used for containing bulk wastes (e.g., contaminated disposables and residual liquids); they may have to be doubled-bagged with polypropylene bags that are heat resistant if steam sterilization (see below) is used. These bags, however, must be opened or of such a nature as to allow steam to penetrate the waste. Color-coded bags are frequently used to aid in the segregation and identification of infectious wastes. Most often red or red-orange bags are used for infectious wastes (hence the term "red bag" waste). An ASTM Standard (#D 1709-75) for tensile strength based on a dart drop test and the mil gauge thickness of the plastic determine its resistance to tearing (62,70). Use of the biological hazard symbol on appropriate packaging is recommended by the EPA to assist in identifying medical wastes. (See figure 1.) In addition, EPA recommends that all of these packages close securely and maintain their integrity in storage and transportation (81).

In general, compaction or grinding of infectious wastes is not recommended by EPA before treatment. Even though it can reduce the volume of waste needing storage, compaction is not encouraged due to the possibility of packages being violated and the potential for aerosolization of microorganisms. Commercially available grinding systems that first involve sterilization before shredding or compaction may alleviate this latter concern (62).[3]

Sharps are of concern, not only because of their infectious potential, but also because of the direct prick/stab type of injury they can cause. For sharps, puncture-proof containers are currently the preferred handling package. EPA recommends these

[1]Studies do exist on needlestick injuries. For example, recent data indicate that approximately 20 percent of all hospital needlestick injuries are due to wastehandling. (See ref. 11; numerous other surveys and studies of needlestick injuries have been conducted, e.g., refs. 45,68).

[2]Although not discussed extensively in this paper, accidental exposure through transportation mishaps is likely to be increasingly a source of concern. If more medical waste is shipped off-site in the future, the potential for accidental spills outside of the generating facility will increase.

[3]Yet, waste haulers note that proper handling of wastes is jeopardized by any compaction that occurs at some point before disposal.

Figure 1.—Biological Hazard Symbol

NOTE: Symbol is fluorescent orange or orange-red, and dimensions are specified for use.

SOURCE: U.S. Environmental Protection Agency, *Guide for Infectious Waste Management*, EPA/530-SW-86-014 (Washington, DC: May 1986).

types of packages for solid/bulk wastes and sharps; bottles, flasks, or tanks are recommended for liquids.[4] In the past, needles were re-capped, chopped, or disposed of by other practices that are no longer common due to their potential for worker injury and, in the case of chopping, for aerosolization of microorganisms during the chopping procedure (62).

New technologies for containing needles and facilitating their safe handling continue to emerge. For example, one company has announced a process which uses polymers to sterilize and encapsulate sharps (and other infectious wastes) into a solid block-like material. A number of companies have also developed encapsulating systems and other sharp disposal processes (e.g., a shredder with chemical treatment of needles and other sharps) (10). These processes may potentially be cost-effective disposal options for doctor offices and other small generators of sharps and other infectious wastes, provided landfill operations would accept the encapsulated wastes.

[4]The CDC has similar recommendations (75,76).

Storage

Storage of the waste needs to be in areas which are disinfected regularly and which are maintained at appropriate temperatures (particularly if wastes are being stored prior to treatment) (62). EPA recommends that storage time be minimized, storage areas be clearly identified with the biohazard symbol, packaging be sufficient to ensure exclusion of rodents and vermin, and access to the storage area be limited (81). The importance of the duration and temperature of storing infectious wastes is noted, due to their association with increases in rates of microbial growth and putrefaction.

The recommendation by EPA for storage of infectious waste is limited, however, to suggesting that "storage times be kept as short as possible" (81). EPA does not suggest optimum storage time and temperature because it finds there is "no unanimity of opinion" on these matters. As the *EPA Guide* notes, there is State variation in specified storage times and temperatures. State requirements often stipulate storage times of 7 days or less for infectious wastes that are unrefrigerated. Sometimes longer periods are allowed for refrigerated wastes.

Transportation

EPA recommendations with respect to the transportation of infectious wastes briefly address the movement of wastes while on-site and in an even more limited way address the movement of wastes off-site. The recommendations are largely limited to prudent practices for movement of the wastes within a facility, such as placement of the wastes in rigid or semi-rigid and leak-proof containers, and avoidance of mechanical loading devices which might rupture packaged wastes (81). Broader issues, such as recordkeeping and tracking systems for infectious or medical wastes once they are taken off-site, and the handling and storage of wastes at transfer stations, have not yet been addressed.

EPA does recommend that hazard symbols "should be in accordance with municipal, State and Federal regulations" (81). Yet, State and Federal agencies have promulgated conflicting or incompatible guidelines with respect to the use of the biohazard symbol and other transportation specifications. States often follow the EPA guidance on the use of the biohazard symbol, but application of

regulations and policies of the Department of Transportation (DOT) and Department of Energy (DOE) may suggest more limited use of the symbol, creating confusion for commercial handlers of medical wastes (43).

DOT has issued regulations for the transportation of etiologic agents. These regulations may apply to most medical wastes contained in packages bearing the biohazard symbol, as a result of the DOT's definition of "etiologic agent" in the *Code of Federal Regulations*.[5] This is a result of the fact that the precise content of most medical waste boxes with a biohazard symbol is not known, but is likely to contain a defined etiologic agent. Further, the DOT regulations specify that packages of this sort be a maximum of one liter in size.

Further, the various classification of medical, and specifically infectious, wastes by different States complicates the interstate shipment of wastes. Depending on the State, a waste may be designated either as a hazardous, solid, or special waste, or simply as freight for the purposes of interstate commerce. Some States have manifest systems, others do not. These factors complicate, but do not prevent, the shipment of wastes within (and outside of) the country. If more medical wastes are shipped between States, which is the apparent trend, the likelihood of accidents will increase. The desirability of more consistent and complete guidelines or regulations regarding the off-site transportation of infectious wastes should be considered in this context.

Potential Occupational Risks

On October 30, 1987, the Department of Labor (DOL) and the Department of Health and Human Services (DHHS) issued a Joint Advisory Notice on "Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)" (80). This Notice goes beyond the CDC guideline changes made in August 1987 that focused on AIDS. Essentially, the universal precaution concept is extended by the Joint Advisory Notice to occupational exposure to Hepatitis B. The Notice advises healthcare workers to assume all body fluids and tissues they come into contact with are infected with a blood-borne disease.

[5]49 CFR 172.401.

Tasks performed by healthworkers are divided into three categories.[6] Category I includes tasks that routinely involve exposure to blood, body fluids, or tissues; Category II tasks routinely do not involve exposure to these substances, but could on occasion (e.g., to administer first aid); and Category III includes tasks that involve no exposure to blood, body fluids, or tissues and for which Category I tasks are not a condition of employment. The Notice also advises that workers should not perform Category I and II tasks before receiving training relating to the facility's standard operating procedures (SOPs), work practices, and protective clothing required for each type of task. (See table 2.)

Special work practices for the disposal of sharps, such as using disposable, puncture-resistant containers to reduce stick injuries, are noted in the Advisory. Further, it recommends that employers should provide free voluntary Hepatitis B immunization for any workers performing Category I tasks who test negative for Hepatitis antibodies. At the request of employees, the employer should have a voluntary program to monitor for Hepatitis and AIDS antibodies following a known or suspected exposure to blood, body fluid, or tissues. This should include confidential medical counseling if they are found seropositive for either virus. Employers are also encouraged to keep records of the training, tasks, etc., of employees engaged in Category I or II tasks. Currently, the CDC estimates that only 20 to 40 percent of healthcare workers are immunized.

In October 1987, DOL/DHHS sent letters to approximately 500,000 healthcare employers to inform them of the Advisory Notice (80). The letter notes that as many as 18,000 healthcare workers per year may be infected by the Hepatitis B virus and several hundred will become acutely ill or jaundiced from the virus. Ten percent will become long-term carriers and as many as 300 healthcare workers may die each year as a result of Hepatitis B infections or complications. The letter also states that the Occupational Safety and Health Administration (OSHA, part of DOL) will respond to employee complaints and conduct inspections to ensure proper procedures are being followed.

[6]It should be noted, that the use of Categories I, II, and III are not required by OSHA, but are used on a voluntary basis.

Table 2.—Joint Advisory Notice on the Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)—Training Program Recommendations

According to the Joint Advisory Notice, "The employer should establish an initial and periodic training program for all employees who perform Category I and II tasks. No worker should engage in any Category I or II task before receiving training pertaining to the Standard Operating Procedures (SOPs), work practices, and protective equipment required for that task."

The training program should ensure that all workers:

1. Understand the modes of transmission of HBV and HIV.
2. Can recognize and differentiate Category I and II tasks.
3. Know the types of protective clothing and equipment generally appropriate for Category I and II tasks, and understand the basis for selection of clothing and equipment.
4. Are familiar with appropriate actions to take, and persons to contact, if unplanned Category I tasks are encountered.
5. Are familiar with and understand all the requirements for work practices and protective equipment specified in SOPs covering the tasks they perform.
6. Know where protective clothing and equipment is kept; how to use it properly; and how to remove, handle, decontaminate, and dispose of contaminated clothing or equipment.
7. Know and understand the limitations of protective clothing and equipment. For example, ordinary gloves offer no protection against needlestick injuries. Employers and workers should be on guard against a sense of security not warranted by the protective equipment being used.
8. Know the corrective actions to take in the event of spills or personal exposure to fluids or tissues, the appropriate reporting procedures, and the medical monitoring recommended in cases of suspected parenteral exposure.

SOURCE: U.S. Department of Health and Human Services, Centers for Disease Control, "Recommendations for Prevention of HIV Transmission in Health-Care Settings," *Morbidity and Mortality Weekly Report*, vol. 36, Aug. 21, 1987.

It is not clear, however, that healthcare and other workers are being adequately informed of the advisory and trained in the new recommended procedures. For example, in California concerns have been raised by some unions over the approach of some healthcare facilities in establishing infection control programs in response to the Joint Advisory Notice. Hospitals and other healthcare employers are reportedly providing "minimal training programs and [may be requiring] workers to sign a form stating that they've been trained [in order] to prevent future liability" to the facility (36,68).

In 1987, OSHA began enforcing some of its existing regulations to respond to the hazard presented by occupational exposure to blood and body fluids. These include regulations for sanitation and waste disposal; personal protection equipment (PPE); housekeeping; sign and tags; and the application of the General Duty Clause of the Occupational Safety and Health Act. A detailed description of this program can be found in OSHA's instructions to its compliance officers (79).

In addition, OSHA sought input through an Advance Notice of Proposed Rulemaking about the need for and content of additional regulations. The Service Employees International Union, AFL-CIO, CLC (SEIU), and the American Federation of State, County, and Municipal Employees (ASFME) petitioned OSHA in September 1986 to issue a standard to protect healthcare workers from potential exposure to Hepatitis B and AIDS and make the Hepatitis B vaccination available to high risk workers free of charge (1,66). OSHA expects to issue regulations by the end of 1988.

SEIU, while waiting for OSHA to respond to their petition, conducted "an informal survey of infectious disease control practices within forty hospital departments in four urban centers experiencing high rates of AIDS infection," the results of which became available in June 1987.[7] (See tables 3 and 4.) The SEIU survey, while not statistically significant due to the small sample size, concluded that "employer voluntary compliance of infection control guidelines is spotty at best, even in healthcare institutions located in urban areas experiencing high rates of AIDS infection" (66). SEIU highlighted several issues relating to the management of medical wastes. For example, it noted that studies of non-healthcare occupational exposures to bloodborne diseases are almost non-existent, but that exposure of these other types of workers to such diseases is known. SEIU, therefore, maintains that the scope of coverage of OSHA regulations should be based on the known modes of transfer (i.e., exposure), not arbitrary occupational and industry sector categories.

The National Solid Waste Management Association (NSWMA) also maintains that solid waste

[7]SEIU represents 850,000 service workers in the public and private sectors, of which 275,000 are healthcare workers in hospitals, nursing homes, and a variety of other health and medical facilities. In addition, at least half of their membership in other types of jobs (this includes workers such as janitors, mortuary and cemetery workers, technicians, and police officers) may be exposed to blood, blood products, body fluids, and injuries from sharps.

Table 3.—Compliance Rates With Joint Advisory Notice—70-Hospital Sample (in percent responding "Yes")

	All hospitals	Hospital size		
		Large	Medium	Small
Personal protective equipment (PPE):				
Gloves readily available	89%	86%	87%	100%
Sufficient quality	67	63	14	60
Right sizes	60	55	60	20
Masks or goggles available	58	46	61	100
Fluid resistant gown available	39	36	48	20
Work practices/equipment:				
Handwashing facilities in vicinity	86%	81%	87%	100%
Ambubags available	63	59	72	40
Needle disposal containers in vicinity	75	67	81	100
Self-sheathing needles	23	26	19	25
Linen red bagged	87	83	91	80
Standard operating procedures:				
Procedures developed	28%	19%	36%	0%
PPE routinely used when contact with bodily fluids is anticipated	56	47	70	60
Training:				
Educational materials	87%	81%	74%	80%
OSHA worker brochure	4	5	0	20
Training in universal bloodborne disease precautions	54	50	63	50
Medical:				
Hepatitis B vaccine available	74%	72%	70%	80%
If available, free of charge	90	85	100	75
Confidential HIV testing available	26	28	26	0
If available, counseling provided	66	70	50	0

SOURCE: Service Employee International Union, AFL-CIO, CLC, "Comments on OSHA's Advance Notice of Proposed Rulemaking to Control Occupational Exposures to Hepatitis B and AIDS" (Washington, DC: Jan. 26, 1988).

Table 4.—Compliance Rates With Joint Advisory Notice—30-Department Sample (in percent responding "Yes")

	Nursing home (8)	Blood bank (2)	Correctional facilities (4)	Med. labs and HMOs (7)	Mental health rehab. clinics (9)
Personal protective equipment (PPE):					
Gloves readily available	50%	100%	100%	100%	89%
Sufficient quality	75	0	100	57	63
Right sizes	25	0	50	57	75
Masks or goggles available	25	100	50	71	56
Fluid resistant gown available	75	100	50	14	44
Work practices/equipment:					
Handwashing facilities in vicinity	63%	0%	75%	100%	78%
Ambubags available	38	0	75	29	63
Needle disposal containers in vicinity	83	0	67	100	63
Self-sheathing needles	0	0	0	14	0
Linen red bagged	75	0	100	43	78
Standard operating procedures:					
Procedures developed	0%	0%	75%	57%	22%
PPE routinely used when contact with bodily fluids is anticipated	12	0	75%	100%	78%
Training:					
Educational materials	50%	50%	100%	86%	0%
OSHA worker brochure	0	0	0	0	0
Training in universal bloodborne disease precautions	75	0	50	71	78
Medical:					
Hepatitis B vaccine available	38%	100%	75%	100%	67%
If available, free of charge	67	100	75	80	57
Confidential HIV testing available	0	0	25	29	22
If available, counseling provided	0	0	25	43	0

SOURCE: Service Employee International Union, AFL-CIO, CLC, "Comments on OSHA's Advance Notice of Proposed Rulemaking to Control Occupational Exposures to Hepatitis B and AIDS" (Washington, DC: Jan. 26, 1988).

workers are at risk and should be covered by OSHA's infectious waste regulations (34). Solid waste workers have been exposed to transmittable diseases on the job through such practices as compaction of untreated wastes in standard refuse vehicles. This can result in the aerosolization of pathogens and potentially lead to disease transmission.

Some observers, however, maintain that such risks are minimal (8,60). They maintain, for example, that if wastes are properly packaged and handled, two of the factors necessary for disease transmission are not present, i.e., mode of transmission and portal of entry. A frequently cited study, performed in West Germany in 1983, does report that there is no microbiologic evidence that biomedical wastes are more infective than residential waste (37). These issues, however, have not been extensively researched in the United States to determine the degree of risks posed by infectious wastes. In any case, those actually working associated with the housekeeping, janitorial, and refuse handling and disposal of medical wastes indicate that packaging frequently (although actual numbers are not available) does not hold wastes, and that workers are exposed. Bags and boxes may leak fluids, or sharps may protrude (51,66).

In general, the establishment of standard operating procedures (SOPs) is regarded as an effective way to better ensure the proper handling, storage, and transportation of medical wastes.[8] For example, the segregation of medical wastes has a critical impact on the handling, storage, and transportation of wastes. EPA recommends that infectious wastes be segregated at the point of origin; that distinctive and clearly marked plastic bags and containers for infectious wastes be used; and the biological hazard symbol be used as appropriate (81). Hospitals tend to segregate wastes into at least infectious and non-infectious groups (61,62). Critical to the proper functioning of this system is knowledge of the waste types and their hazards by healthcare workers, and their cooperation to segregate the wastes.

Even though segregation of wastes is considered key to a successful waste management program, it is also generally regarded as a highly problematic practice. That is, there is some difficulty in ensuring that healthcare workers will reliably segregate wastes. In part this results from the fact that, understandably, "most nurses and physicians consider the delivery of health care to be their primary mission," not sorting wastes into [seemingly] arbitrary categories (58). For this reason some hospitals apparently find it easier to designate all wastes from certain areas of the hospital as infectious.

Although this approach may be more costly, given that disposal costs for infectious waste are generally higher than those for general refuse, it does minimize the chances for crossover of infectious waste into the general wastestream (58,62). If all the wastes are mixed, then they would probably be considered infectious and managed as such (i.e., sterilization or incineration v. landfilling or sewer use). Once again, the central importance of the definition of medical wastes becomes apparent. The hospital's definitions of wastes affects the segregation of the wastes within the hospital and their handling, treatment, and ultimate disposal.

[8]See, e.g., ref. 17. It is certainly an important aspect of the approaches recommended by CDC, OSHA, and EPA for medical waste management.

Chapter 3
Current Technologies, Treatment, and Disposal Issues

Incineration

The incineration of medical waste has many of the same advantages and disadvantages associated with the incineration of any type of waste. That is, advantages include significant volume reduction of the wastes, while requiring little processing of wastes before treatment. Disadvantages include high costs and potential pollution risks associated with incineration processes. The discussion in this chapter will focus on issues and concerns more specific to the incineration of medical wastes.

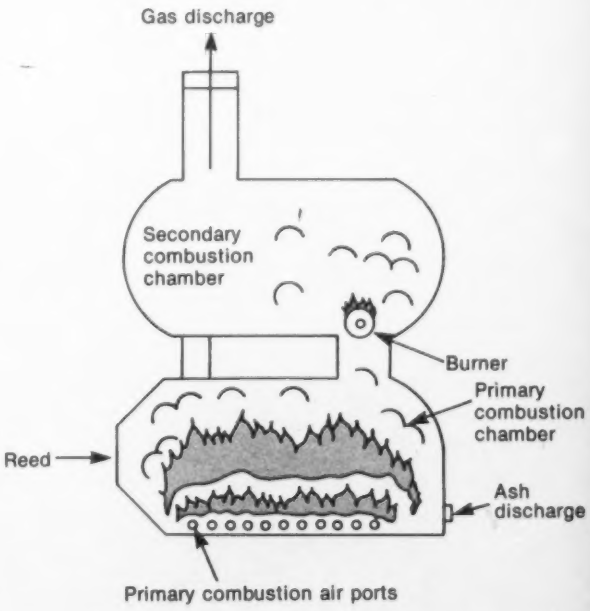
As noted earlier, hospitals generate approximately 2.1 to 4.8 million tons of medical waste per year (9,83). Of that, about 10 to 15 percent, or about 210,000 to 720,000 tons, is generally considered infectious waste. Hospitals often incinerate both infectious and non-infectious waste together. The total amount of medical waste incinerated per year is unknown.[1] In fact, the exact number of medical waste incinerators currently operating is not known.[2]

Hospital incinerators burn a much smaller volume of waste than municipal incinerators. Of the 158 million tons of municipal solid waste generated per year, approximately 15 million tons are incinerated (15). What concerns some observers is that many of the hospital incinerators are located in heavily populated areas (which could lead to greater potential exposure) and appear to have relatively high emission rates of some pollutants of concern given their size.

Limited data indicate that small, on-site incinerators can emit relatively high levels of some pollutants, but few risk assessments have been performed on these incinerators, hindering the ability to definitively evaluate the relative degree of risks from these sources compared with other sources. Most hospital incinerators have short stacks, which may allow incinerator emissions to enter hospitals through air-conditioning ducts and windows (40). One study found that the concentrations of chromium, cadmium, and 2,3,7,8 tetra-chlorinated dibenzo-p-dioxin (TCDD) equivalents were approximately two times higher in the hospital air intake than the maximum ambient ground level concentrations (13).

The three types of incinerators used most frequently for hospital waste treatment in the United States are: controlled air, multiple chamber air, and rotary kiln models (83). (See figure 2.) All three types can use primary and secondary combustion chambers to ensure maximum combustion of the

Figure 2.—Typical Controlled Air Incinerator



SOURCE: C. Brunner, "Biomedical Waste Incineration," paper presented at 80th Annual Meeting of the Air Pollution Control Association, New York, NY, June 1987.

[1]EPA estimated that the total amount of hospital waste incinerated, when including the waste incinerated off-site, is about 80 percent of the total hospital waste in the United States (42).

[2]One estimate is that over 7,000 medical waste incinerators of the most frequently used type, i.e., controlled air systems, have been installed during the past two decades (8).

waste. Many hospitals also may have small (usually older) incinerators used only for pathological wastes.[3] Most, probably over 90 percent, of the hospital incinerators installed during the last two decades have been controlled air units, which tend to be modular (8). Large municipal incineration operations are usually of a different design, since often more capacity is needed than a modular unit can provide. Consequently, there are relatively fewer modular municipal waste incinerators.

As noted above, some concerns associated with the incineration of medical wastes are not unlike those associated with the incineration of most municipal solid wastes (e.g., the effects of burning plastics). Other concerns are more specific to the medical wastestream, such as the highly mixed nature of medical wastes (e.g., infectious, hazardous, and general refuse wastes) and the potential for incomplete pathogen destruction. Both types of concerns will be discussed in this section, although limited data are available on either type of concern. First, the types of incinerators most frequently used for medical wastes will be briefly discussed and compared.

Controlled Air Incinerators

Most of the incinerators built for medical waste treatment in the last 15 to 20 years have been controlled air (sometimes referred to as starved air) incinerators. These burn waste in two or more chambers under conditions of both low and excess stoichiometric oxygen requirements. In the primary chamber, waste is dried, heated, and burned at between 40 and 80 percent of the stoichiometric oxygen requirement. Combustible gas produced by this process is mixed with excess air and burned in the secondary chamber. Excess air is introduced into the secondary chamber at usually between 100 and 150 percent of the stoichiometric requirement. A supplementary fuel burner is used to maintain elevated gas temperatures and provide for complete combustion.

Temperatures in the incinerator are controlled through adjustments in the air levels. Air in both chambers is modulated to maintain proper operating temperatures. Furnace exit temperatures are usually maintained in the normal range between 1,400 and 2,000 °F. There are also three and four stage-controlled air incinerators that feature flue gas recirculation.

One advantage of using low levels of air in the primary chamber is that there is very little entrainment of particulate matter in the flue gas. For example, multiple-chamber air incinerators have average particulate emission factors of 7 pounds per ton, compared with 1.4 pounds per ton for controlled air units. Available data indicate that many controlled air incinerators can be operated to meet existing particulate standards that are at or below 0.08 grains per dry standard cubic foot (gr/dscf) (corrected to 12 percent carbon dioxide) (3,83). Many States, however, are adopting lower standards (e.g., 0.015 gr/dscf) for incinerators, which probably would require additional control technologies. Additional controls may raise capital costs and require expansion space (which may or may not be available). Additional controls, however, would capture finer particulates and some other pollutants.

Advantages of the controlled air system include high thermal efficiency as a result of lower stoichiometric air use, higher combustion efficiencies, and low capital costs (which may increase as more controls are required). As with all types of incinerators, disadvantages include potential incomplete combustion under poor operating conditions and problems associated with achieving proper operating temperatures during startup of a batch unit.[4]

Other Types of Incinerators

Most incineration systems constructed before the early 1960s were of the multiple-chamber types (sometimes referred to as excess air types). They operated with high excess air levels and thus needed scrubbers to meet air pollution control standards (8). Few multiple-chamber incinerator units are being installed today. Instead, older units of this type are used primarily for non-infectious wastes (3,8).

A small number of rotary kiln incinerators are currently operating, although greater use of them is being promoted by some. These incineration systems feature a cylindrical, refractory-lined (usually brick) combustion primary chamber. This chamber

[3]It is not known how many of these types of incinerators are still in use.

[4]In batch units, the waste is placed in the furnace in batches and allowed to burn out. Combustion of the waste first occurs in the primary (ignition) chamber, through the introduction of heat by a burner.

rotates slowly (between 1 and 3 rpm) on a slightly inclined, horizontal axis. This rotation provides excellent turbulence (i.e., mixing). Yet, the rotary kiln systems tend to be costly to operate and maintain, usually require shredding (i.e., some size reduction of wastes), and usually require emission controls (3,8,83).

Variations of all types of incineration processes and other "innovative" technologies continue to appear. At present, however, controlled air incinerators are popular due to their relatively low (capital, operating and maintenance) cost and their ability to meet *existing* air standards without air pollution controls. As a result, the controlled air incineration industry is healthy. It remains in a relatively constant state of change and development, although there are frequent turnovers, mergers, and company failures in the industry (8).

Air Emissions and Ash

Concentrations of Emission Constituents[5]

As of 1987, most States recommended but did not require control of opacity and particulate emissions from hospital incinerators (83). The reported range of concentrations of constituents in hospital incinerator emissions are presented in table 5. The raw data on emissions can be analyzed by normalizing the data to the amount of waste burned. Table 6 shows that for both polychlorinated dibenzodioxins (PCDDs, commonly referred to as dioxins) and polychlorinated dibenzofurans (PCDFs, commonly referred to as furans), hospital incinerator emissions are on the average one to two orders of magnitude higher per gram of waste burned than emissions from municipal incinerators. The single exception to this is the Hampton, Virginia, facility, which in the past emitted upper bound dioxin and furan levels that are one order of magnitude higher than the upper bound levels reported for hospital incinerators.[6]

Thus, hospital incinerators tend to produce more dioxins and furans per gram of waste burned than municipal incinerators. Given the smaller volume of medical waste incinerated, overall emissions from all medical waste incinerators are less than those from existing incinerators. Yet, since hospital incinerators are usually located in densely populated areas, potential exposure may be greater.

Table 5.—Concentrations of Constituents in Emissions From Hospital Incinerators Without Particulate Control Devices

Constituent	Range of emissions[a]
Arsenic	1-5.99 gr/dscf
Cadmium	24.7-140 gr/dscf
Chromium	2.15-30.9 gr/dscf
Lead	532-1190 gr/dscf
Nickel	2.22-8.0 gr/dscf
TCDD	3.3-38.5 ng/Nm³
Total dioxins	51.8-450 ng/Nm³
TCDF	18.9-79.8 ng/Nm³
Total furans	117.3-785 ng/Nm³
HCl	41-2095 ppmv
SO_2	19-50 ppmv
NO_x	155-270 ppmv

[a]Abbreviations: gr/dscf = grains per dry standard cubic foot; ng/Nm³ = nanograms per standard cubic meter; ppmv = parts per million volume.

SOURCE: U.S. Environmental Protection Agency, "Hospital Waste Combustion Study, Data Gathering Phase," final draft, October 1987.

Table 6.—Dioxin and Furan Emission Concentrations (in ng/Nm³)

Facilities	Total dioxins	Total furans
Hospitals:[a]		
A	160-260	386-700
B	290-450	700-785
C	117-197	52-84
Municipalities:		
Hampton, NY	243-10,700	400-37,500
North Andover, Mass.	225	323
Marion Co., Oregon	1.13	
Prince Edward Island, Canada	60-125	100-160
Tulsa, Okla.	18.9	15.5
Wurzburg	22.1	27.9
Akron, Ohio	258	679

[a]Exact locations of hospitals were not reported in the study.

SOURCE: C.C. Lee, G. Huffman, and T. Shearer, "A Review of Biomedical Waste Disposal" (U.S. Environmental Protection Agency, Feb. 19, 1988).

[5]Additional data may soon be available as a result of a settlement approved by the U.S. District Court of the District of Columbia between EPA and two environmental groups. The settlement includes a requirement for EPA to study emissions of dioxins and durans from hospital incinerators, the current regulations of State and local governments, and available control technologies of such emissions by January 31, 1989. By March 3, 1989, EPA is to complete a study of operating procedures for hospital incinerators. (See *Environmental Defense Fund and National Wildlife Federation v. Thomas*, Civ. No., 85-0973 (D.D.C.))

[6]The Hampton facility has recently been retrofitted, and its emissions have been significantly reduced (46).

Possible Reasons for Higher Emission Levels of Dioxins/Furans and HCl

Higher concentrations of dioxins and furans may be associated with medical waste incineration emissions due to:

1. the frequent startups and shutdowns these incinerators undergo;
2. less stringent emission controls;
3. poorer combustion control (e.g., waste mixing and oxygen controls); and
4. differences in the waste feed composition as compared with municipal solid waste.

Studies have shown that dioxins and furans can be formed *after* leaving the furnace, by the catalysis *at low temperatures* of precursors (such as chlorophenol and benzene) and chlorine atoms on fly ash particles (19). This suggests that destruction of precursors in the furnace and control of temperatures in the stack are important factors in preventing formation of dioxins and furans. Disagreement exists over whether pyrolysis of PVC in hospital incinerators can produce chlorobenzene (a potential dioxin precursor). EPA has studied the phenomenon of "transient puffs" (referring to upset conditions) in test incinerators burning PVC and polyethylene. During waste charging, hospital incinerators often experience high carbon monoxide emissions, indicating poor combustion. These transient puffs generate large quantities of products of incomplete combustion (PICs), including dioxins (40).

Almost all hospital incinerators are operated on an intermittent basis (83). Frequent startups and shutdowns of medical waste incinerators may lead to increased dioxin formation and may volatilize certain waste components, including pathogens. A study of dioxin emissions from the Westchester municipal incinerator in New York State found that during cold starts (without auxiliary fuel), dioxin and furan emissions were at least 10 times higher than under normal operation (14,38). The study concluded that dioxins are formed in cool sections of the incinerator (between 400 and 800 °F). If startups and shutdowns of medical waste incinerators are undertaken without auxiliary fuel, poor combustion may allow dioxin precursors (e.g., chlorophenols) to escape up the stack, increasing catalysis of dioxins and furans on fly ash particles.

A study by the New York State Energy and Research Development Authority (NYSERDA), however, found that the presence of polyvinyl chloride (PVC) was not related to the levels of dioxins and furans in the stack of a municipal incinerator, at least under the limited set of conditions during the test. Instead, formation of these compounds was partly related to the thoroughness of the combustion process. Poor combustion, which occurred at temperatures below 1500 °F and which was indicated by high carbon monoxide levels, resulted in substantial increases in dioxin and furan formation in the furnace (52).[7]

Moreover, differences in waste composition may influence the formation of dioxins and furans through increased concentrations of precursors. Medical waste can contain organic solvents that may act as aromatic precursors and chemicals such as anti-neoplastic agents (classified as RCRA hazardous waste) and bactericides. In addition, cytotoxic wastes represent approximately 1 to 2 percent of all hospital wastes (71).

Laboratory studies have found that pyrolysis of various plastics produces chlorinated aromatic hydrocarbons. For example, pyrolysis of PVC has resulted in the formation of benzene, 1,1,1-trichloroethane, trichloroethylene, and tetrachloroethylene (85). On this basis, it is conceivable that pyrolysis of plastics may occur in the primary combustion chamber of controlled air units, causing the formation of dioxin and furan precursors. To reduce formation of these precursors, increased turbulence (mixing), retention time, and temperature are required (7). In addition, computerized combustion controls that regulate the level of oxygen in the furnace can improve destruction of precursors (40).

The concentrations of hydrogen chloride (HCl) also appear to be consistently higher, on average, compared with municipal waste combustors. One reason for this may be higher levels of PVC in medical waste (39).[8] EPA has reported that plastics comprise approximately 20 percent (by weight) of all hospital waste, compared with 5 to 10 percent in municipal solid waste (55). Virtually all of the chlorine present in these wastes is converted to HCl dur-

[7]See refs. 2,65.

[8]It should be noted, however, that HCl is contained primarily in PVC and not other types of plastics. OTA does not have data on how much PVC is in the plastic portion of the medical wastestream.

ing the actual combustion process, assuming a high combustion efficiency. The chlorinated plastics may contribute to some of the high emission rates of HCl and possibly dioxins. HCl may be controlled by monitoring waste input or through the installation of appropriate air pollution control technologies (e.g., acid gas scrubbers).

Concentrations of Constituents in Ash

Little data has been reported describing the concentrations of the constituents of medical incinerator ash. Heavy metals have been found in hospital incinerator emissions and are expected to be present in incinerator ash. Lead and cadmium, for example, are found in radioisotope shielding as well as pigments and additives in plastics (40). Limited data from one hospital showed that extractions of the fly ash sample were well above EP Toxicity limits for cadmium and lead. Extractions from the bottom ash sample were well below EP Toxicity limits (7). One study summarized dioxin and furan concentrations in fly ash from three hospital incinerators and four municipal incinerators (19). (See table 7.) The data reveal that concentrations of both dioxins and furans are considerably higher in hospital incinerator fly ash than in municipal incinerator fly ash.

Total dioxin levels in hospital incinerator fly ash samples were between 1 and 2 ppm, which is much higher than the range of 7 to 80 ppb for the municipal fly ash samples. (See table 7.) In addition, none of the fly ash samples from the hospital incinerators had concentrations of the 2,3,7,8-TCDD isomer alone that were below 1.4 ppb. A concentration of 1.4 ppb of **total** 2,3,7,8-TCDD equivalents is the figure that CDC and EPA Headquarters have used as an indicator of safe concentrations of dioxin in ash. If total toxic equivalents are calculated, hospital incinerators actually exceed the dioxin standards by about two orders of magnitude. It is important to note, however, that this comparison is based on a limited sample, and caution is required when attempting to draw any conclusions based on the reporting of so few studies.

Table 7.—Concentrations of Dioxins and Furans in Fly Ash From Municipal and Hospital Incinerators (ng/g, equivalent to parts per billion)

	Incinerator type	
Constituent	Municipal	Hospital
2,3,7,8-TCDD	0.03-0.34	1.4-3.4
Tetra CDD	0.6-7.5	94-404
Penta CDD	1.2-13.2	208-487
Hexa CDD	1.4-15.8	271-411
Hepta CDD	1.8-25.6	189-307
Octa CDD	1.9-23.1	123-245
Total dioxins	6.9-80.3	1155-1737
Tetra CDF	9.0-32.1	199-376
Penta CDF	10.2-38.3	285-647
Hexa CDF	8.0-31.7	253-724
Hepta CDF	3.4-15.9	125-286
Octa CDF	0.7-4.6	25-134
Total furans	31.3-119.5	895-2140

SOURCE: H. Hagenmaier, M. Kraft, H. Brunner, and R. Haag, "Catalytic Effects of Fly Ash From Waste Incineration Facilities on the Formation and Decomposition of Polychlorinated Dibenzo-p-dioxins and Polychlorinated Dibenzofurans," *Environment, Science and Technology* 21(11): 1080-1084, 1987.

Future Trends in Medical Waste Incineration

There are a number of factors (in addition to the definitional issues discussed above) which may influence the waste disposal practices of hospitals in the future. First, the stringency of the emission standards that hospital incinerators will need to meet will determine the type and cost of air pollution controls. The cost and engineering feasibility of retrofitting existing hospital incinerators with acid gas scrubbers and/or particulate matter controls, and computerized combustion controls, may force many hospitals to cease on-site incineration in favor of off-site centralized incineration.[9] The *capital* costs of larger regional incinerators are presumed to be lower per ton of waste than smaller individual hospital incinerators (6). Other costs, such as transportation, however, need to be considered. Also, generators of wastes using a regional facility rather than incinerating wastes on-site may not realize a cost savings.

Second, increased regulation of ash disposal may provide further impetus for hospitals to utilize off-site management of wastes or residuals. Even those hospitals that continue to incinerate wastes on-site may be forced to contract with a centralized ash management facility. It is unlikely that disposal of

[9]See, for example, refs. 6,39); Currently, insurance is apparently available for hospital incinerators (e.g., refs. 27,31) and financing for construction of off-site facilities is also available (18). Future concerns in these areas do exist as well as concerns over potential siting problems and other difficulties associated with the construction of most waste facilities of any type today.

incinerator ash in existing municipal landfills will continue to be allowed. This may result in the need to send the ash to more stringently controlled landfills or monofills. Regardless of whether ash is regulated under either Subtitle C or as a special waste under Subtitle D, relatively short-term liability costs associated with RCRA corrective action as well as longer term liability associated with Superfund could increase insurance and other operating costs for these ash disposal facilities.

Controlled air incinerators have traditionally been popular for medical wastes. As noted above, this is apparently due to the fact that they can achieve relatively lower particulate emissions, as compared with rotary kiln incinerators (which tend to be higher priced due at least in part to the need for emission controls, such as fabric filters or electrostatic precipitators) (3). As best available control technology (BACT) emission standards below 0.08 gr/dscf for particulate matter (PM) are promulgated, however, controlled air facilities will require additional emission controls and may lose one cost advantage over rotary kiln models.

For example, New York recently proposed PM standards for new hospital incinerators of 0.01 gr/dscf for facilities processing more than 50 tons per day and 0.015 gr/dscf for facilities processing less than 50 tons per day, as well as a standard of 0.03 gr/dscf for existing facilities. In contrast, the new Pennsylvania PM standard is 0.08 gr/dscf for modular facilities, which can probably be met by many controlled air facilities without emissions controls. Mid-sized units must meet 0.03 gr/dscf and large units must meet 0.015 gr/dscf. The 0.03 and 0.015 standards will require air pollution control devices.

Alternative technologies are being studied for medical waste disposal. For example, the Department of Energy announced its participation in a demonstration project at a hospital in Pennsylvania to incinerate hospital wastes with coal in a fluidized bed boiler. The temperatures at which coal burns in these combustors is about 1,600 °F, which is considered sufficient to render most medical waste noninfectious. Limestone is added to the bed to absorb sulfur. Moreover, both the limestone and the coal ash itself, are chlorine-capturing agents. The fluidized bed combustion could allow hospitals to incinerate waste on-site and also to produce energy for heat, steam, or other hospital uses (64).

Autoclaving

Autoclaving, or steam sterilization, is a process to sterilize medical wastes prior to disposal in a landfill.[10] Since the mid-1970s, steam sterilization has been a preferred treatment method for microbiological laboratory cultures. Other wastes (e.g., pathological tissue, chemotherapy waste, and sharps) may not be adequately treated by some sterilization operations, however, and thus require incineration (72). OTA has no data on the total amount of medical wastes sterilized in the country.

Typically, for autoclaving, bags of infectious waste are placed in a chamber (which is sometimes pressurized). Steam is introduced into the container for roughly 15 to 30 minutes. Steam temperatures are usually maintained at 250 °F (63). Some hospital autoclaves, however, are operated at 270 °F (61). This higher temperature sterilizes waste more quickly, allowing shorter cycle times.

Several studies indicate that the type of container (e.g., plastic bags, stainless steel containers), the addition of water, and the volume and density of material have an important influence on the effectiveness of the autoclaving process (41,54,63). Each of these factors influences the penetration of steam to the entire load and, consequently, the extent of pathogen destruction. Autoclaving parameters (e.g., temperature and residence/cycle time) are determined by these factors.

Since there is no such thing as a "standard load" for an autoclave, adjustments need to be made by an operator based on variation in these factors. As with many technologies, proper operation of autoclaves is key to effective functioning (i.e., in this case, sufficient pathogen destruction to render wastes non-hazardous).

One method of assuring that pathogen destruction has taken place is the use of biological indicators, such as *Bacillus stearothermophilus*. Elimination of this organism (as measured by spore tests) from a stainless steel container requires a cycle time

[10]Ethylene oxide and other gas sterilization processes, as well as some chemical (including the use of radioactive) processes, are also used to treat wastes.

of at least 90 minutes of exposure. This is considerably longer than is currently provided by standard operating procedures (61,63). This conservative approach, however, may provide more pathogen destruction than is necessary to reduce microbiological contamination to non-infectious levels (63).

Chemical disinfection (e.g., with formaldehyde, xylene, alcohol) is used to sterilize reusable items. Recently, sodium hypochlorite has been used in a process to disinfect disposable products. Partial destruction of the material is achieved, but additional incineration and high capital costs are associated with the process as well.

Several factors have led some hospitals to abandon autoclaving. For example, problematic operating conditions can lead to incomplete sterilization. In addition, landfill and off-site incinerator operators are increasingly refusing to receive such wastes, questioning whether the waste has actually been treated. The refusals are partly in response to the fact that most autoclaved "red bags" do not change color and thus appear no different from non-autoclaved red bags (even though they often are labeled or in some way identified as "autoclaved"). This also has led to more cumbersome documentation and/or identification requirements in an effort to avoid refusals (72).

Incineration v. Autoclaving; and the Importance of Proper Operation

Autoclaves must achieve minimum temperatures and be operated according to appropriate cycle times to ensure adequate destruction of pathogens. Primary and secondary chamber temperatures of 1,400 °F and 1,600 °F, respectively, must be reached in hospital incinerators to ensure adequate combustion and minimum air emissions (83). Normally, these temperatures would ensure the destruction of pathogens in the waste, however, if an incinerator is loaded and fired-up cold, pathogens could conceivable escape from the stack. Data is not readily available to evaluate this point further. At the typical operating temperature of an autoclave (250 °F), the cycle time of 45 to 90 minutes is necessary to reduce pathogen concentrations in most hospital waste below infectious levels (63).

The proper operation of incinerators and autoclaves is critical to their effective functioning. Proper operation is dependent on at least four conditions: 1) trained operators; 2) adequate equipment (i.e., proper design, construction, controls and instrumentation); 3) regular maintenance; and 4) repair. For example, trained operators need to be knowledgeable in the operation of the incinerator and in the proper handling of medical wastes. It is not clear, however, that workers are consistently receiving adequate training in the operation of incinerators or autoclaves, and consequently that most units are operating properly.[11]

Autoclaves do provide some advantages over incinerators, which may increase their attractiveness as a disposal option, particularly if incineration regulations become much more stringent and thereby increase incineration costs. For example, operation and testing of incinerators is more complex and difficult than that for autoclaves (57). In addition, environmental releases from incinerators probably contain a broader range of constituents (e.g., dioxins, heavy metals) than autoclaves.

Autoclaves are also less costly to purchase and operate and require less space. These cost advantages, however, may be lessened if incineration is also required.

A major difficulty associated with autoclaving is the reluctance of landfill and (off-site) incinerator operators to accept medical wastes. This, along with other difficulties associated with autoclaving, such as ensuring the proper operation of the autoclaving process (e.g., sufficient residence time to ensure pathogen destruction), the more limited capacity of most autoclaves, and the time-consuming process for autoclaving compared with incineration, make it a less common waste treatment method for most facilities (53).[12]

[11]EPA is preparing a training manual for the operators of hospital incinerators and an air compliance inspection guide.

[12]Recently, new technologies for autoclaving have been announced. For example, one company has introduced a large mobile autoclaving unit (moved on a semi-trailer) that can sterilize approximately 1,500 pounds of waste per hour. Materials "cook" at 275 °F and are then allowed to cool. Special autoclaving bags are apparently not necessary, and the process is advertised as an economical disposal option for certain medical wastes. See announcement in *Infectious Waste News*, June 18, 1987.

Health and Environmental Risks From Treatment Technologies[13]

The few risk assessments that have been performed on individual hospital incinerators have predicted health risks (specifically, cancer risks) that are comparable to those predicted for municipal incinerators (20,47). Important differences, however, in risk assessment methodologies and the site-specific nature of these risk assessments precludes meaningful comparisons between projected cancer risks. For example, most risk assessments account for risks associated with inhalation, but not for those associated with ingestion. In addition, the age of facilities under investigation varies considerably, and older facilities tend to have less-than-optimal operating conditions and/or less air pollution control equipment.

There are two important points regarding hospital incinerator emissions: 1) hospital incinerators do not generally achieve emission levels as low as those reported for municipal incinerators; but 2) they tend to burn a much smaller volume of waste and so emit smaller quantities of toxic constituents. Yet, the closer proximity of many hospital incinerators to populations is also an important consideration. In any case, no national estimates have been developed for aggregate cancer risks from all hospital incinerators that can be compared with EPA's national estimates for municipal incinerators. Additionally, no national estimates of non-cancer effects associated with hospital incinerator emissions have been undertaken.

[13]Note, currently most of the attention here is on risks from the incineration of biomedical wastes. Additional information, as available, will be added on risks associated with autoclaving and landfilling.

The risks associated with incinerator emissions have been estimated by States for individual municipal incinerators and by EPA for all municipal incinerators (48,82). In contrast, few risk assessments have been performed for hospital incinerators. The New Jersey Department of Environmental Protection (N.J. DEP) performed a risk analysis on four hospital incinerators for seven carcinogens (four metals, two VOCs and TCDD), HCl, and criteria pollutants (20). Only TCDD was found to pose a cancer risk of greater than one in a million. The upper bound cancer risks from chromium and cadmium, the second and third most significant carcinogens, were both one order of magnitude lower than TCDD.

A risk analysis of a proposed hospital incinerator in Michigan predicted upper bound dioxin cancer risks that were one order of magnitude lower than those predicted by N.J. DEP (12). The New Jersey risk assessment only examined the tetra dioxin homolog and did not include other dioxin homologs or furans in the analysis. This may have resulted in some underestimation of the upper bound cancer risk. One review of data on dioxin and furan emissions from hospital incinerators has found emission rates of total dioxins and total furans generally higher than those from municipal incinerators (42).

The New Jersey results are consistent with the national risk assessment performed by EPA on municipal incinerators insofar as they indicate that dioxins are responsible for most of the cancer risk associated with incinerator emissions (82). EPA's analysis, which examined the risk from municipal incinerators on a national basis, found that dioxins posed the greatest risk of cancer by two orders of magnitude, compared with the second most significant carcinogen present, cadmium.

Chapter 4
Regulatory Authority and Current Practices

Federal Authority

The two Federal laws that most directly provide the government with the authority to regulate or control the management of infectious wastes in some way are the Resource Conservation and Recovery Act (RCRA) and the Occupational Safety and Health Act (OSHA).[1] In addition, New Source Performance Standards (NSPS) of the Clean Air Act may apply to hospital incinerators.[2] Any special State and local regulations for general and infectious wastes also apply. Certain chemical wastes generated in healthcare facilities are considered hazardous waste and may be subject to provisions of RCRA, and radioactive waste disposal must conform with Nuclear Regulatory Commission standards.[3]

The agency with the most comprehensive authority to provide Federal leadership on the management of medical wastes is EPA. EPA has authority under RCRA to regulate the handling, storage, treatment, transportation, and disposal of medical wastes. Its regulations would apply to public and private facilities of all types.

Currently, as noted above, the Agency has only issued a guidance document for the management of infectious wastes. Other medical wastes are considered to be like any other solid waste and are subject to relevant RCRA Subtitle D regulations.

In contrast, the CDC does not have authority to issue regulations. OSHA may issue regulations or guidelines to protect the health and safety of workers, but they apply only to private facilities (unless a State extends the coverage to employees of public facilities as well).[4] At present, OSHA does regulate employee exposure to toxic substances under the General Industry Health standards.[5]

Under Section 6 of OSHA, the Labor Secretary is given general authority to promulgate such standards in order to assure the "attainment of the highest degree of health and safety protection of the employee." Yet, the feasibility of the standards must be considered, and they must be set on the basis of the best available evidence. There is apparently nothing in the definitions of terms in OSHA that would preclude the application of the law's authority to the regulation of infectious wastes.[6] At this time, however, OSHA has limited its specific activity on occupational exposure to infectious wastes to its rulemaking activity to control occupational exposures to Hepatitis B and AIDS.

State Regulatory Activities

Given the general lack of regulation on the national level, States have developed their own infectious or medical waste programs. As the Council of State Governments (CSG) report, *State Infectious Waste Regulatory Programs*, notes, without a Federal baseline and without Federal funds "to support the creation of a new environmental regulatory program [to manage infectious wastes], states, *regardless of size or location*, are in the process of meeting the public's demand for protection. It is [a] clear state-generated initiative . . ." (emphasis added) (4). Local governments (e.g., towns, cities, and counties) may also develop special medical requirements of one sort or another. This has led to tremendous variation in the regulation of these wastes.

The variation in State activities is worthy of Federal attention for at least two reasons. First, stricter regulations in one State may encourage the shipment of wastes to other States with less stringent regulations. Second, many States, in the absence of Federal guidance, apparently are "leap-frogging" one another to adopt the most stringent regulations. One of the most striking features of recent State action on medical/infectious waste issues is its rapidity. As the CSG notes, many

[1] 42 U.S.C. 6901 et seq.; 29 U.S.C. 651 et seq., respectively.

[2] 42 U.S.C. 7411. It is important to note that NSPS apply only if the source is over 50 tons per day, which few medical facilities are. In any case, these standards only apply to conventional criteria pollutants. Potential air toxics are not regulated at the national level at this time.

[3] 40 CFR 260-265; 122-124; 10 CFR 20, respectively. These types of wastes, because of their need to be handled specially and the existence of regulations governing their disposal, will not be discussed extensively here.

[4] 29 U.S.C. 652(5); 655(b); 657(c); 657(g)(2).

[5] 29 U.S.C. 655.

[6] The definiton of the term employer appears sufficiently broad to include hospitals and possibly other generators; the definition of "toxic materials or harmful physical agents" also appears broad enough to include infectious wastes (21 CFR 1910.20(c)(11)). See ref. 16.

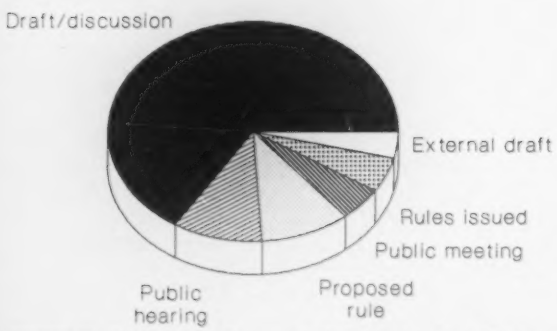
State legislative sessions are only a few months long and only meet every other year. Yet, States have been responding quickly to public concern over medical wastes: 88 percent of the States in 1988, compared with 57 percent in 1986 are or will be regulating infectious wastes (4). (See figure 3.)

Eleven States split the jurisdiction over infectious wastes between solid waste management offices and health department offices, while other States designate one or the other of these types of offices as the lead authority. Enforcement authority is usually in the solid waste office for off-site disposal, with the air pollution control board responsible for regulating incinerator emissions, and with the hospital licensure office responsible for monitoring on-site generation, treatment, and disposal of infectious wastes. Seven States delegate this authority to county health departments, and in five it is delegated to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (4).[7]

A majority of States target hospitals in their regulation of infectious wastes. Of these, three-quarters also regulate clinics, but only half also include doctor and dental offices, veterinary hospitals, and other small generators (4). (See figure 4.) Five States currently exempt or are proposing to explicitly exempt small quantity generators from infectious

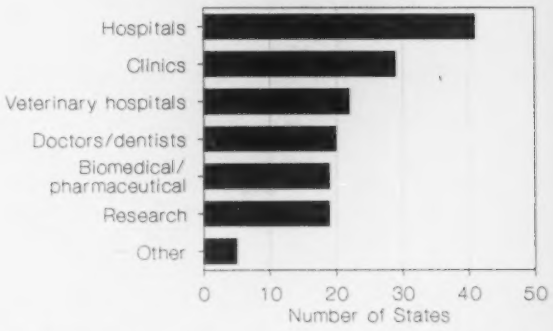
[7]The JCAHO inspects hospitals periodically and determines their accreditation. Despite their recognized authority, and potential to effect the waste management practices of hospitals, there has been criticism of the thoroughness of their inspections. See, e.g., ref. 53.

Figure 3.-Stages of State Changes in Medical Waste Management Programs-As of March 1988



SOURCE: The Council of State Governments, *State Infectious Waste Regulatory Programs* (Lexington, KY: 1988).

Figure 4.-Types of Medical Waste Generators Regulated by States-As of March 1988



SOURCE: The Council of State Governments, *State Infectious Waste Regulatory Programs* (Lexington, KY: 1988).

waste regulations or policies (4).[8] Regulating infectious wastes on the basis of listed generators versus types of wastes can lead to some important incongruities. In Rhode Island, for example, wastes from animal research in a laboratory associated with a hospital are subject to infectious waste regulations, however, wastes from animal research at a laboratory unaffiliated with a hospital are not subject to the regulations (4). As will be discussed further below, whether small quantity generators should be exempt from infectious waste regulations is a significant, unresolved issue.

Unless a State specifically regulates infectious wastes as hazardous wastes (4),[9] permits are not likely to be required by States. Instead, infectious waste guidances and rules appear to be the norm and are designed to be "self-enforcing." The Council of State Governments identifies the logic as:

> Best management practices (emphasizing biosafety), liability issues, and haulers' refusals to handle red-bagged wastes are recognized and depended upon as strong voluntary compliance inducements (4).

A concern expressed by some hospital administrators, however, is that the regulations proposed or adopted by some States are inappropriate, unrealistic, and costly. For example, the New York State Department of Environmental Conservation's

[8]These are: California, Indiana, Minnesota, Missouri, and Ohio.

[9]This is true for: the District of Columbia, Hawaii, Iowa, Kentucky, Maine, and Washington.

(DEC) draft regulations, referred to as the "most far-reaching and comprehensive waste management laws in the nation" for solid and infectious waste management, contain the following incinerator emission standards:

- 0.010 grains per dry standard cubic foot of flue gas, corrected to 7 percent oxygen (for new facilities processing over 50 tons/day);
- 90 percent reduction of hydrogen chloride (HCl) emissions;[10]
- At least 1 second residence time at least 1,800 °F for combustion gas.[11]

These new regulations are expected by many, including the DEC, to increase the cost of on-site incineration of infectious wastes (31). This may lead to more off-site treatment of hospital wastes.

One hospital consultant's opinion of the New York State regulations, and other State regulations, based on best available control technology for incineration of infectious wastes is that:

> . . . [they] appear to have no technical basis, and many are also reflective of unproven, unrealistic, and sometimes unattainable technology . . . . . What appears most disturbing, however, is that there appears to be no evidence or documentation which show that there will be any significant environmental benefits or reduced health risks if such proposed legislation is enacted (8).

He maintains that more analysis is needed before such standards are adopted. The need for standards set on the basis of sound analysis is rarely disputed. Currently, lacking such an analysis, it is unclear which level of standards are most appropriate. Variation between the levels adopted by States is readily evident, however, and is one justification frequently noted for the development of national standards. (See table 8.)

[10]Unless it is demonstrated that either the stack concentration is less than 50 parts per million by volume, dry basis corrected to 7 percent oxygen; or, the uncontrolled emission rate is less than 4 pounds per hour and the total charging rate is less than 500 pounds per hou

[11]For multichamber incinerators, these parameters must be met aft.. the primary combustion chamber, which must be maintained at no less than 1,400 °F.

More than half of the States require or plan to require treatment (e.g., autoclaving) of infectious wastes before land disposal. Yet, under certain conditions, at least 12 States allow infectious wastes to be landfilled without treatment. Seventy-two percent of the States name incineration in their existing or proposed regulations as a recommended treatment for medical wastes. Five States *require* incineration (4).[12] Twenty-three States are considering establishing performance standards, which could be in addition to any other applicable standards set by State air control agencies for incinerators. Twenty-seven States recommend steam sterilization as a treatment process for infectious wastes. Fourteen of these States specify or are considering specifying time/temperature/pressure standards. Eighteen States include chemical treatment as an alternative, and other treatment alternatives are considered on a case-by-case basis by other States (4).

Handling of infectious wastes on-site is usually governed by State health departments. They issue guidelines usually based on the periodically issued recommendations on biosafety from JCAHO, CDC, NIH, EPA, and OSHA (4). Packaging and labeling requirements are included in the infectious waste regulations of 31 States. These include such requirements as rigid containers, double bagging, and labeling requirements. Storage requirements (currently in place in 7 States and being considered by 14 others) include such elements as the length of time wastes can be maintained on-site and refrigeration requirements. Transportation requirements (including the designation of only non-compacting trucks for transporting infectious wastes, requiring truck labeling and shipping procedures, and specifying cleaning procedures) and recordkeeping requirements (usually recordkeeping by the generator rather than a manifest system of submitting records to the State) are being considered by three-fifths of the States (4).

[12]These are: Alaska, Arkansas, Colorado, New Hampshire, and Tennessee.

Table 8.—Status of Selected State Infectious Waste Incinerator Regulations[a]

Parameter	New York	Pennsylvania	Minnesota	Mississippi	California	Wisconsin
Air emissions:						
Particulates	0.01 gr/dscf (for new and old facilities over 50 tons/day); 0.015 (for new facilities if less than 50 tons/day); 0.03 (for existing facilities if less than 50 tons/day	0.1 gr/dscf (for existing facilities); 0.08 gr/dscf (for new facilities less than 500 lbs/hr); 0.03 (for facilities of 500-2000 lbs/hr); and 0.015 (for facilities over 2000 lbs/hr)	0.01 gr/dscf (for facilities less than 1000 lbs/hr)	0.2 gr/dscf (at 12% CO_2)	0.1 gr/dscf at 12% CO_2 (for existing facilities); 0.08 (for new facilities)	0.03 gr/dscf at 12% CO_2 for greater than 200 lbs/hr)
Visible emissions (opacity)	Hourly average 10% maximum content, 6 minutes average less than 20%	30% (anytime 10% for any 3 minute hourly average)	—	40%	20%	5% (as measured by U.S. EPA Method 9
HCL (acid gas)	90% HCl reduction, or 50 ppm HCl	30 ppm (or 90% reduction)	Testing required	—	—	50 ppm at 12%
SO_2	50 ppm	30 ppm (or 75% reduction	—	—	—	CO_2 over any continuous 1 hour period
Carbon monoxide	Hourly average no more than 100 ppm at 7% O_2	Hourly average no more than 100 ppm at 7% O_2	—	—	99%	75 ppm at 7% reduction
Combustion:						
Efficiency	—	99.9%	—	—	—	—
Operator training:						
Training	Yes	Yes	—	—	—	Yes
Certification	Yes	—	—	—	—	
Solid waste:						
Residual burn out	—		—	—	—	Maximum ash content 5%, no visible unburned combustibles

Abbreviations: gr/dscf = grains per dry standard cubic foot; ppm = parts per million [a]Many States are currently revising their regulations for infectious waste incineration. These figures should not be cited without confirming their current status.

SOURCE: Adapted from F. Cross, "Comments on Background Paper," prepared for OTA Workshop on Biomedical Waste Management (Washington, DC: July 19, 1988); R. Kerr, New York State Department of Environmental Conservation, personal communication, Sept. 20, 1988; J. Salvaggio, Pennsylvania Department of Environmental Resources, personal communication, Sept. 20, 1988; and Gary Yee, California Air Resources Board, personal communication, Sept. 21, 1988.

Chapter 5
Managing Medical Wastes—Institutional and Policy Issues

Whether the Federal Government should further regulate the management of medical/infectious wastes is an open issue. Within the policy debate over whether and how medical wastes should be regulated are classic divisions between those maintaining there is a need to *document* actual harm from medical wastes, and those primarily concerned with the *potential* harm posed by these wastes. Most environmental laws passed in the last 20 years have embodied a "preventive" approach to human health and environmental risks as the basis for regulatory action. In practice, however, a more "reactive" basis for policy development is often used. This latter approach reflects the incomplete shift of the "burden of proof" with which administrative agencies have had to cope in justifying the actual regulation of environmental practices. This pragmatic approach to regulation, in an effort to conserve regulatory resources, essentially finds regulation justified only when the relative degree of risks posed by the activities are known and appear high. It is in this context that the debate takes place over whether current management problems associated with medical waste disposal warrant Federal regulation.

At the moment, two regulatory trends are emerging in medical waste management, both primarily driven by the more "preventive" mode of regulation: one trend is toward regulating greater quantities of potentially infectious wastes; and the other trend is toward tightening controls over incineration and other disposal options. As one hospital consultant noted,

> More and more waste quantities are required to be treated as "infectious," of which smaller percentages are truly infectious; but, simultaneously, viable treatment and disposal options are being eliminated or made cost-prohibitive (8).

The concern of some generators of medical waste is that some, if not all, "viable" management options will become less available (or more costly) due to the adoption of stricter air emission regulations by a number of States. This could affect, at least on a temporary basis, the availability of sufficient capacity in some areas for managing medical waste.

Several other general trends also appear to be emerging in the management of medical wastes. These include: 1) the likelihood of further regulation, at least at the local and State levels of government; 2) possible increases in off-site commercial and regional incineration facilities, depending on the levels of standards set in such regulations and on other cost factors; 3) an increase in the transportation of medical wastes if there is more off-site disposal (which will probably provide further impetus to establishing manifest or recordkeeping systems of some sort);[1] and 4) the likelihood of increased costs for disposing of medical wastes as more treatment becomes necessary and more stringent controls are adopted.

As noted above, most States are currently developing or revising regulatory programs that address medical wastes. The stringency of the emissions standards that medical incinerators must comply with will determine the type and cost of necessary air pollution controls. **The cost and engineering constraints (e.g., space) of retrofitting existing hospital incinerators with acid gas scrubbers and/or particulate matter controls may force many hospitals to cease on-site incineration in favor of off-site incineration at regional, centralized facilities.** Regional facilities, however, are likely to face siting difficulties.

Increased transportation of medical wastes to regional facilities, or to facilities that are located outside a State and in some cases outside of the country, will further increase disposal costs. It is also

[1]Ontario, Canada, has a manifest system in place and would like the United States to establish a manifest system of some sort to facilitate estimating better the amounts of medical wastes entering Canada from the United States, in order to better plan for the management of it. Some States (e.g., Massachusetts, New York, Missouri, and New Jersey) are establishing or have established manifest systems of some sort for medical wastes.

likely to increase health risks to the public, given the greater potential for accidental exposure due to spills and possible illegal dumping or disposal. **These concerns provide support for proposals that require manifest or recordkeeping systems to track the movement of these wastes.** The Senate passed legislation (S. 2680) in August 1988 that will require EPA to establish a model tracking system in New York, New Jersey, and Connecticut for medical wastes. Similar legislation is pending in the House (H.R. 3515, H.R. 5119).

Policy Issues for Federal Action

To best address issues associated with these trends, at least two types of policy activities are relevant: 1) further development and enforcement of standard operating procedures (SOPs) by hospitals and other medical waste generators for the handling, storage, treatment, and disposal of these wastes; and 2) further clarification and coordination of regulatory programs at the local, State, and Federal levels of government. In particular, the possibility of further Federal involvement warrants discussion, given the increased public concern over the management of medical wastes, the increased level of local and State regulatory activity (which has led to nationwide variation in the treatment of these wastes), the interstate transportation of medical wastes, and the current absence of a comprehensive medical waste policy at the national level.

The Federal Government could usefully specify its policy(ies) regarding medical wastes in a number of areas: 1) designation of a lead authority (presumably EPA) to clarify the definition, classification, and regulation of these wastes; 2) the establishment of emission standards and ash regulations for medical waste incinerators, autoclaving/landfilling performance standards, and possibly operator training guidelines/regulations; 3) handling, storage and transportation guidelines/regulations to ensure worker safety and possible establishment of some sort of a manifest system; and 4) research and data needs on medical waste practices. Some of these issues could be addressed under RCRA's current authority or could be clarified as part of the RCRA re-authorization process.[2] Other relevant laws are OSHA, the Clean Air Act, and possibly the Toxic Substances Control Act.

A number of important, related issues noted throughout this paper re-surface as the implications of these areas for possible further policy development are discussed. The implications of three of these areas, the definition/classification of medical wastes, the issue of small quantity generators of medical wastes, and research and data needs associated with medical waste management are discussed briefly to indicate the range of regulatory issues the Federal Government will need to address if it revises or expands its role in medical waste management.

The definition of medical wastes under RCRA is of critical importance to determining the type of regulatory effort EPA is likely to undertake. Its clarification is also likely to facilitate State actions and commercial development of medical waste incineration. Another important dimension of the medical waste management issue is which types of sources should be regulated, i.e., the question of whether small generators of medical wastes should be exempted. Further research into the nature of the risks (both occupational and environmental) associated with medical wastes, research on new treatment technologies, and performance data for existing facilities is desirable in order to develop more informed and effective policies.

Defining/Classifying Medical Wastes

If infectious wastes are classified and regulated as hazardous under RCRA, a comprehensive management program is likely for infectious wastes. For example, regulating infectious wastes as hazardous wastes under RCRA could address transportation issues associated with infectious waste management. This would involve: 1) recordkeeping concerning the waste transported, its source and delivery points; 2) transportation of the waste only if properly labeled; 3) compliance with the manifest system (Section 3002); and 4) transportation only to

[2]Some issues, e.g., concerning occupational risks, could be addressed under other statutory authority, such as OSHA. The focus here is on RCRA given the primary focus of this paper on waste disposal issues.

the waste facility that the manifest form designates as holding a proper permit.[3] In addition, waste treatment, storage, and disposal facilities would be subject to hazardous waste standards and permitting procedures.[4]

As the Council for State Governments (CSG) has noted, existing State infectious waste programs do not tend to include three requirements usually associated with hazardous waste laws. These are requirements for contingency plans and spill management, closures, and financial assurances (4).

As noted above, in RCRA, the statutory definition of hazardous waste includes "infectious" as a defining characteristic.[5] EPA interprets RCRA as providing it with discretionary authority to classify infectious wastes as either hazardous wastes or solid wastes.[6] EPA, in 1978, did include infectious waste as part of its first set of proposed hazardous waste regulations. The final rule published in 1980, however, stated that infectious waste regulations would be published separately. As the CSG notes,

> . . . [e]ight years and two reauthorizations of RCRA later, still no Federal regulations have been promulgated (4).

Instead, in 1986, the EPA issued its *Guide for Infectious Waste Management* stating that

> . . . [w]hile the Agency has evaluated management techniques for infectious waste, considerable evidence that these wastes *cause* harm to human health and the environment is needed to support Federal rulemaking (emphasis added; 81).

RCRA (Section 1004), however, states that the term "hazardous waste" refers to a waste with infectious characteristics which may

> . . . *pose* a substantial present or potential hazard to human health or the environment . . . (emphasis added).

Recently, EPA has increased its attention to infectious and medical waste issues. In early 1988, EPA assigned for the first time a full-time staff person to handle infectious waste issues. In June, the Agency issued a request for comment on infectious waste issues in the *Federal Register*. Most recently the Agency has formed a task force to address infectious waste issues. Publicly, the Agency has not ruled out the possibility that ultimately it may issue regulations, although at present its efforts seem to be on developing an education program.

As noted above, infectious wastes are unlike other types of hazardous wastes that can be consistently identified by a test. Detection of infectious microbes in landfill leachate is not highly likely given that they are generally less persistent in the environment than toxic substances such as heavy metals, oils, solvents, etc. Exposure to sunlight or dry air can render infectious wastes non-infectious. It is also true, however, that infectious microbes in medical wastes could multiply and are potentially contagious under certain conditions. In this context, developing a separate statutory category for infectious and medical wastes is seen by some observers as desirable. Applicable hazardous waste provisions from RCRA Subtitle C could be adopted and appropriate adjustments made given the particular nature of the medical wastestream.

It is not entirely clear how EPA may ultimately define, classify, and regulate infectious wastes (or if it will). As noted above, EPA's June 2, 1988, *Federal Register* request for comment on infectious wastes issues indicates the initiation of some information gathering action on this issue. EPA's position in the summer of 1988 was that an education program, but not regulation, was justified. Later in 1988, after several congressional hearings, EPA announced that it would consider the need for Federal regulation and established a task force on medical waste issues.

Meanwhile, Congress, as part of the RCRA reauthorization process, will address the issue of infectious and medical waste management (H.R. 3515; S. 2773).[7] H.R. 3515 is the more detailed

[3] 42 U.S.C. 6924.

[4] 42 U.S.C. 6924; 6925.

[5] 42 U.S.C. 6903(5).

[6] 42 U.S.C. 6903(5); 6921. The hazardous characteristics, of which infectious is one, listed in 6903 are to be considered when the Administrator of EPA identifies or lists hazardous wastes as per 6921. EPA, however, in their regulatory interpretation, left the infectious characteristic out of the definition of "hazardous waste" (40 CFR 240.101(m)).

[7] The House Energy and Commerce Subcommittee on Transportation, Tourism, and Hazardous Materials held one hearing October

(continued on next page)

of the two bills with respect to medical waste management. For example, it would require EPA to issue regulations for all aspects of infectious waste management including generation, transportation, treatment, storage, and disposal.

H.R. 3515 distinguishes between medical and infectious wastes. Infectious wastes would only be classified as hazardous wastes under this bill if they were mixed with hazardous wastes already regulated under Subtitle C. In September 1988, a substitute for H.R. 3515 added a provision to establish a demonstration tracking system for medical waste in New York, New Jersey, Connecticut, and the Great Lakes States.[8] As of September 21, 1988, the House Energy and Commerce Committee was scheduled to "mark up" H.R. 3515.

A number of other bills regarding medical waste management issues have been introduced. As indicated in table 9, the proposed pieces of legislation address a number of aspects of medical waste management, beyond the definition and classification issues. Some significant action on several of the bills appears likely before the current session of Congress ends.[9]

Regulating Small v. Large Generators of Medical Wastes

Whether incineration emission standards should be set at the Federal level and on what basis (tech-

(continued from previous page)
21, 1987, on the regulation of infectious wastes. The House Small Business Subcommittee on Regulation and Business Opportunities held a hearing on August 9, 1988, on medical waste issues.

[8]The Senate passed legislation (S. 2680) which would establish a model tracking system for New York State, New Jersey, and Connecticut. Similar legislation (H.R. 5119), in addition to H.R. 5215, is pending in the House.

[9]For example, a bill (H.R. 5231) to amend the Marine Protection, Research and Sanctuaries Act (Public Law 92-532; MPRSA, commonly referred to as the Ocean Dumping Act) of 1972 is expected to reach the floor of the House before the end of the current session. The bill would increase criminal penalties for illegal ocean dumping of medical waste and provide recovery of damages associated with illegal dumping. The Senate included similar provisions in the amendments of MPRSA (S. 2030) that it passed in August 1988.

Table 9.—Legislation Pending in Congress on Medical Wastes (as of Sept. 20, 1988)[a]

Bill number	Sponsor (original)	Brief summary
H.R. 1156	Dwyer (D-NJ)	Permits citizens of one State to bring Federal civil action against any person in another State creating a public nuisance through improper management of medical wastes
H.R. 3467	Rinaldo (D-NJ)	Requires that within 12 months after completing a study of infectious and pathologic waste, EPA must determine whether to regulate these wastes as hazardous wastes under Subtitle C of RCRA
H.R. 3478	Saxton (D-NJ)	Amends MPRSA (Public Law 92-532). Bans the dumping of medical wastes in ocean and navigable waters
H.R. 3515	Luken (D-OH)	Amends RCRA (Public Law 94-580) to require EPA to regulate the management of infectious and medical wastes; provisions include definition of waste types by EPA, and establishment of a model manifest system in New York, New Jersey, Connecticut, and the Great Lake States
H.R. 3595	Hughes (D-NJ)	Requires vessels to manifest the transport of municipal or other nonhazardous wastes to ensure they are not illegally disposed of at sea
H.R. 5119	Florio (D-NJ)	Amends RCRA to regulate medical wastes by requiring EPA to establish a model tracking system for New Jersey and New York
H.R. 5130, 5225	Hughes (D-NJ)	Amends U.S.C., Title 18, to provide penalties for illegal ocean dumping of medical wastes
H.R. 5231	Studds (D-MA)	Amends MPRSA to increase criminal penalties for illegal ocean dumping of medical wastes and provide for recovery of damages associated with illegal dumping
H.R. 5249	Davis (R-MI)	Purpose is to protect the Great Lakes from the improper disposal of medical wastes
H.R. 5302	Hertel (D-MI)	Establishes a pilot program for the tracking of medical wastes in States bordering the Great Lakes
S. Res. 470	Riegle (D-MI)	A resolution relating to medical wastes improperly disposed of in the Great Lakes
S. 1751	Lautenberg (D-NJ)	Requires vessels to manifest the transport of municipal or other nonhazardous wastes to ensure they are not illegally disposed of at sea
S. 2628	Lautenberg (D-NJ)	Amends RCRA to establish a pilot program to track medical wastes in New York and New Jersey
S. 2726	Dodd (D-CT)	Amends RCRA to require EPA to regulate medical wastes
S. 2773	Baucus (D-MT)	Amends RCRA to define infectious waste and the basis for regulating infectious waste

Abbreviations: EPA = U.S. Environmental Protection Agency; MPRSA = Marine Protection, Research, and Sanctuaries Act (also referred to as the Ocean Dumping Act); RCRA = Resource Conservation and Recovery Act (also referred to as the Solid Waste Disposal Act); U.S.C. = United States Code

[a]The Senate passed legislation (S. 2680) in August 1988, which would establish a model tracking system for New York State, New Jersey, and Connecticut. The Senate also passed in August amendments to MPRSA (S. 2030) that include a provision prohibiting the dumping of medical waste in the oceans and navigable waters. Similar bills (H.R. 3515, H.R. 5119, H.R. 3478, H.R. 5231, respectively) are pending in the House.

nology- or health-based) is an open issue, as is whether small generators (e.g., doctor offices, home care) should be exempt from medical waste regulations. While hospitals and clinics may generate larger quantities of wastes, those generated by smaller facilities may be more susceptible to direct public exposure. The two incidents of children playing with untreated wastes in the summer of 1987, which focused national attention on medical waste management, occurred outside of doctor offices—not hospitals (32).

A problem is how these smaller generators can efficiently and economically dispose of their infectious wastes. Commercial off-site facilities may not be readily available or may be highly costly. Hospitals which could accept the waste (if there are not State or local regulations prohibiting it) may be reluctant to do so for potential liability reasons. Some hospitals allow affiliated doctors to dispose of infectious wastes, and potentially funeral homes (with crematories) could also accept wastes from doctor offices. Again, liability issues and other factors (e.g., the additional staff time for handling such waste) may make these types of facilities reluctant to accept such wastes.

The relative risk posed by wastes from home-care patients and other infectious materials generated in homes versus that produced by commercial generators is not known. Although the public's general concern about AIDS and infectious wastes has led to a focus on hospital wastes, most treatment of AIDS is apparently done on an out-patient basis.[10] As hospital stays have generally become shorter in recent years, home care of patients has increased. Infected wastes from these individuals, as well as such items as disposable diapers and feminine sanitary products, are potentially infective wastes, and they are directly landfilled in most cases. Information on appropriate packaging and special disposal procedures may be one way to encourage prudent disposal of home-care infectious wastes.[11]

It is not clear, however, whether these wastes, any more than it is clear whether hospital wastes (especially those which have been treated by autoclaving or some other sterilization process), pose a significant contamination problem when landfilled.[12] EPA has noted that no groundwater impacts associated with landfilling any medical wastes have been identified to date (84). Yet, with little information on the quantities of infectious waste from small generators, as well as on the risks of these wastes, it is an open question as to what types of controls are appropriate. Controls could focus on handling and direct exposure (through improper disposal) and/or on environmental risks from disposal of these wastes.

The feasibility of controlling small quantity generators presents another policy dilemma.[13] Currently, the confusion over how best to address this issue is evident in proposed legislation in some States. California, for example, has two bills pending, one of which (S. 1448) would prohibit *any* person from disposing of untreated infectious wastes; the other (S. 2469) requires the disposal of sharps in puncture-proof containers, *except* those from private homes, physicians' offices, or health-care facilities.

Research and Data Needs

As noted throughout this paper, little data exists on the management of medical waste. Indeed, the "vital signs" for medical waste management are thereby difficult to read or interpret. **Basic information on sources, amounts, composition, and treatment/disposal of medical waste is not known in any useful detail.** In addition, insufficient research data exist to determine to what degree medical wastes are a public health problem. Information on occupational exposure to hazards associated with managing these wastes is not available. Comprehensive data on the operation of incinerators (e.g., types, comparisons of air emissions levels for a range of pollutants (including patho-

[10]It is also worth noting that CDC studies found that HIV does not persist well in the environment, at least not after drying, which causes a 90 to 99 percent concentration reduction within several hours. See ref. 77.

[11]For example, puncture-proof containers could be provided with the sale of syringes (which in many areas can only be purchased with a prescription) (48a).

[12]Items such as disposable diapers and feminine sanitary products are not generally considered a serious source of infectious contamination to landfills. It is on this basis that some observers maintain that these wastes do not warrant special waste handling procedures, and that bans of these products are unjustified.

[13]The Association for Practitioners in Infection Control has recently proposed a guideline for infection control in home-care which covers waste treatment in this setting (69).

gens), ash content analysis, etc.) do not exist at this time.

As Ode Keil, Joint Commission on Accreditation of Healthcare Organizations, noted at the OTA Workshop on Medical Waste Management, held July 19, 1988, "We have a problem, but we do not have a scientific analysis of the problem to support development of a rational system." **It appears it would be highly prudent for Congress and Federal agencies to address the inadequacy of data and research, and therefore information, on medical wastes and their management. This is essential for determining the need for and nature of any regulatory program for medical wastes.**

A number of possible areas for further research and information gathering exist. Several key areas include:

1. developing the basis for a consistent, concrete definition of medical wastes, which all relevant Federal agencies issue jointly or at least adopt;
2. the nature and extent of occupational risk, including risks not only to healthcare workers, but housekeeping, maintenance and other relevant workers as well;
3. use and comparison of different incineration processes and other technologies, including emission rates and health risk assessments of these disposal options;
4. examination of the use of sewers for medical waste disposal (e.g., the survival of viruses in sewer discharges; problems associated with combined sewer overflows, such as beach washups of medical wastes; etc.);
5. identification of potential waste reduction options for medical facilities; and
6. comparisons of State regulatory programs, specifically to highlight experiences relevant to the development of possible Federal programs (e.g., model programs for managing medical wastes from small generators; manifest systems, etc.).

Concluding Remarks

This chapter highlights the types of regulatory issues that could be clarified by Congress and/or the EPA and other Federal agencies when examining the adequacy of current medical waste management policies. One critical need that is readily apparent and rarely disputed with respect to medical waste management is the need for more information on the risks posed by these wastes and on their actual management, and for more research of alternative treatment technologies and management techniques. **Nonetheless, the need for research should not be taken as a suggestion for postponing consideration of adopting a comprehensive regulatory program to address medical waste management. In fact, research efforts could be a part of a regulatory program, if it is promulgated in phases.**

The most coherent Federal policy for medical waste management is likely to result only if the variety of issues (e.g., the definition, classification, nature of risks, types of available disposal options, and the implications of regulatory action) discussed in this paper are *comprehensively* addressed. At a minimum, this preliminary assessment of the status of medical waste management practices in the United States today indicates that to adequately address the public's growing concern over the management of medical wastes, policymakers will need to address these issues as expediently as possible.

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